TAB 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Plaintiffs, v. MICRO-TECH ENDOSCOPY USA INC., MICRO-TECH (NANJING) CO., LTD., and HENRY SCHEIN INC., Defendants.	C.A. No. 18-1869-CFC-CJB

PLAINTIFFS' FINAL INFRINGEMENT CONTENTIONS

Pursuant to Paragraph 16 of the Court's Scheduling Order in this case (D.I. 29), Plaintiffs Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "Plaintiffs") submit the following as their disclosure of their final infringement contentions, setting forth their infringement charts relating the Accused Devices to the asserted claims of U.S. Patent Nos. 7,094,245 ("the '245 patent"), 8,974,371 ("the '371 patent) and 9,980,725 ("the '725 patent) (collectively the "Patents-in-Suit").

I. Asserted Patents and Claims

Defendants Micro-Tech Endoscopy USA Inc.'s, Micro-Tech (Nanjing) Co., Ltd.'s, and Henry Schein Inc.'s (collectively, "Defendants") manufacture, use, sale, importation, and or offer for sale of their Hemostatic Clip products, including but not limited to the following:

- The SureClip™ Hemostasis Clip line of products (including, without limitation, the SureClip™, SureClip™ MINI, SureClip™ Max, SureClip™ "Shortest Stem" and SureClip™ PLUS Hemostasis Clips), which have been purportedly sold with two different "attachment configurations" (see discussion below)—the attachment configuration as originally sold in the United States (together with the DuraClip™ Hemostasis Clip line of products discussed below, the "Accused Original Devices") and a later version that

Defendants refer to as the "Buckle" configuration (the "Accused Buckle Devices") (together, the "Accused Original/Buckle Devices")[1];

- The DuraClip™ Hemostasis Clip line of products (included in the definition of "Accused Original Devices")[2];

- The LOCKADO™ Hemostasis Clip line of products (the "Accused Lockado Devices"[3]; the above Accused Original, Buckle, and Lockado Devices collectively the "Accused Devices");

result in direct infringement, contributory infringement, and/or active inducement of infringement of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c), including at least infringement of claims 1, 3, 7, 13, and 15 of the '245 Patent, claims 8 and 9 of the '371 patent, and claims 1–3, 6, 8–12 of the '725 patent (collectively, the "Asserted Claims"). For example, Defendants' manufacture, use, sale, importation, and/or offer for sale of the Accused Devices has directly infringed and will in the future directly infringe the asserted apparatus claims of each of the Patents-in-Suit. Additionally, Defendants' activity regarding the Accused Devices has also indirectly infringed and will indirectly infringe the Asserted Claims of the Patents-in-Suit by

[1] These products include, without limitation, products manufactured, used, sold, imported, and/or offered for sale under UPN #s RC30101, RC30105, RC30141, RC30145, RC30381, RC30385, RC30411, RC30415, RC30441, RC30445, RC30541, and RC30545.

[2] These products include, without limitation, products manufactured, used, sold, imported, and/or offered for sale under UPN #s DC0165, DC0235, and DC0235W.

[3] Defendants have not, to date, produced any discovery related to the sale or offer for sale of the Accused Lockado Devices. However, on information and belief and to the best of Plaintiffs' knowledge, these products include, without limitation, products manufactured, used, sold, imported, and/or offered for sale under reference numbers LOCK-C-26-195-C, LOCK-C-26-230-C, LOCK-D-26-195-C, LOCK-D-26-230-C, LOCK-F-26-195-C, LOCK-F-26-230-C, LOCK-C-26-195-C-S, LOCK-C-26-230-C-S, LOCK-D-26-195-C-S, LOCK-D-26-230-C-S, LOCK-F-26-195-C-S, LOCK-F-26-230-C-S, LOCK-C-26-195, LOCK-C-26-230, LOCK-D-26-195, LOCK-D-26-230, LOCK-F-26-195, LOCK-F-26-230. *See, e.g.*, Micro-Tech Endoscopy LOCKADO™ Clip, http://micro-techmedical.com/products/sup_11.html (last accessed July 31, 2020).

inducing others to use infringing products and/or inducing others to perform all of the steps of the claimed methods. In particular, Defendants actively encourage others to use, and specifically intend them to use, the Accused Devices as intended and instructed in the Instructions For Use of the Accused Devices. In such instances, physicians (and/or other medical personnel, such as, for example and without limitation, the nurses, physicians' assistants, and other medical personnel working in or with the operating room, endoscopy unit, and/or gastroenterology unit of a hospital or other surgical center), acting alone or in combination with one another, perform each and every step of the methods of treatment recited in the asserted method claims and use the claimed apparatus of each of the Patents-in-Suit, with the active encouragement and specific intent of Defendants. To the extent the steps of the claimed methods are performed by more than one such person, the persons performing the steps have been and will be acting at the direction and control of a single entity (such as the hospital, surgical center, medical group, or other corporate entity that employs or contracts with each of them) or a single person (such as the attending physician or other medical professional in charge of the treatment of the patient) and/or as part of a joint enterprise (e.g., between and among the medical personnel and the hospital or other medical facility in which the patient is being treated). Defendants have knowledge of the Patents-in-Suit, and by virtue of their Instructions for Use and other conduct, they have actively and intentionally induced and will in the future actively and intentionally induce such infringement. Further, the Accused Devices are specially adapted, material parts of the claimed methods of treatment that have no substantial non-infringing uses, such that Defendants' manufacture and sale of the Accused Devices also contributes to such infringement.

II. Infringement Claim Charts

Exhibits A, B, and C attached hereto set forth Plaintiffs' infringement claim charts for the Asserted Claims of the Patents-in-Suit against the Accused Devices, providing Plaintiffs' infringement contentions on a limitation-by-limitation basis for each of the Patents-in-Suit. Plaintiffs contend the Accused Devices and performance of the claimed methods using the Accused Devices as described in the attached charts literally infringes each Asserted Claim. In the alternative, Plaintiffs contend the Accused Devices and performance of the claimed methods using the Accused Devices infringe under the doctrine of equivalents as described in the attached charts.[4]

The documents and evidence identified in the charts are exemplary only, and are not an all-inclusive list of evidence in support of Defendants' infringement of the Asserted Claims. All references to a particular document or section of a document in Plaintiffs' infringement contentions include any subsequent supplements or updates to the section or document. Furthermore, citation to specific page(s) of documents is for illustrative purpose only and does not preclude reliance on additional pages from the same document.

III. Supplementation and Amendment

Discovery is ongoing, and Plaintiffs anticipate that the subject matter of these infringement contentions will be the subject of further fact and extensive expert discovery. Accordingly, this disclosure is based on the information available to Plaintiffs and the discovery that it has been able to conduct as of the date of this disclosure. Plaintiffs reserve the right to

[4] Plaintiffs reserve the right to contend infringement under the doctrine of equivalents with respect to any limitation that Defendants allege is not literally met for each Asserted Claim of the Patents-in-Suit.

amend any of its disclosures to the full extent consistent with the Court's Rules and Orders, as additional discovery is pursued, additional information is obtained from Defendants, and the investigation and analysis by any expert consultants proceed. Plaintiffs reserve the right to further modify and/or supplement these contentions with additional or different theories and/or additional or different evidence.

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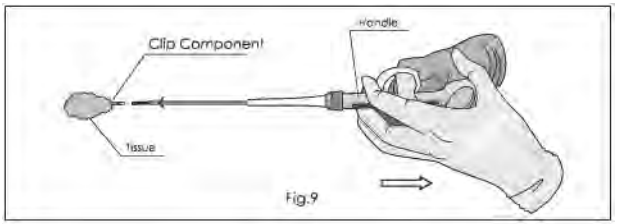
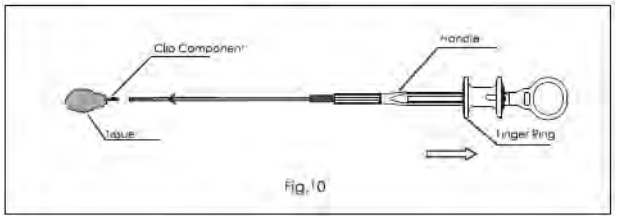
EXHIBIT A

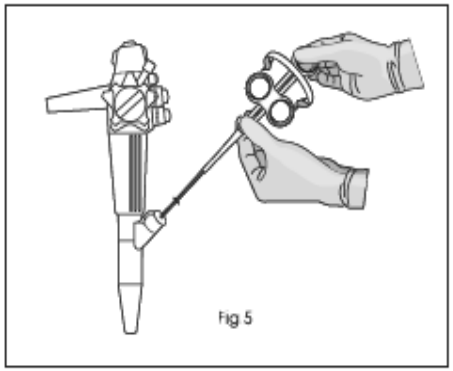
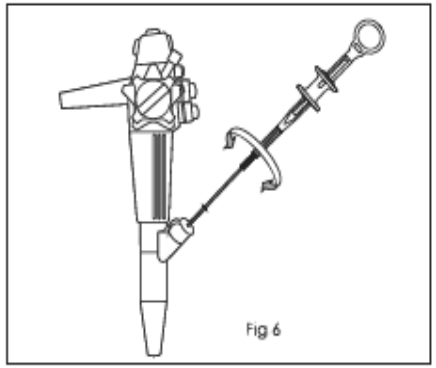
Patent No. 7,094,245; Claim 1	**Micro-Tech Hemostasis Clip**
A medical device for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising:	The Court has construed the preamble of this claim to be limiting. *See* D.I. 140. Each of the Accused Devices is a hemostasis clip for use through an endoscope. *See, e.g.*, Micro-Tech USA SureClip™ Repositionable Hemostasis Clip Instructions for Use (Exhibit 1), at 1 ("The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract"); *see also, e.g.*, MT00000039; MT00000093-104.
a clip, the clip having at least two clip legs;	The Court has construed "a clip" to be a "multi-legged grasping device." *See* D.I. 140. Each of the Accused Devices includes a clip that is comprised of two clip legs located at the distal end of the device, as shown, e.g., in the exemplary picture below. The clip is a multi-legged grasping device as described below. The clip legs are linked together and caused to open and close, in part, by a distal pin and a proximal pin. The proximal pin is located near the proximal ends of the clip legs. The distal pin travels along a cam path (slot) in the proximal section of the clip legs, the slot extending through each clip leg as the clip moves between an open position and a closed position. Forces applied distally to these clip legs via the control wire and breakable link cause the clip legs to open; forces are thereafter applied proximally as needed to receive target tissue therebetween. *See, e.g.*, Micro-Tech USA SureClip™ Hemostasis Clip Data Sheet (Exhibit 2), at 1. Such movement is reversibly operable prior to uncoupling. *See, e.g.*, *id.* at 2 ("SureClip's unique design permits opening and closing the jaw prior to deployment.").

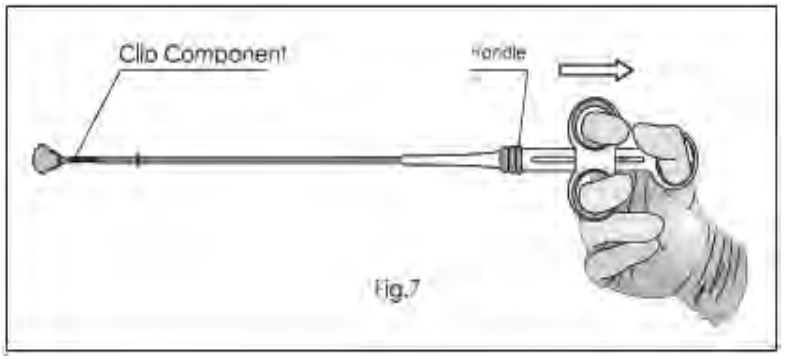
	 *See also, e.g.*, MT00000149.
a breakable link adapted to couple a control wire to the clip and adapted to be broken by a first predetermined tensile force applied by the control wire;	The Court has construed "breakable link . . . adapted to be broken" as "a component of the device designed to mechanically fail by fracturing at a predetermined tensile load." D.I. 140. For each Accused Original/Buckle Device, a pair of J-shaped (original)/C-shaped (buckle) hooks (each, a "Hook," and collectively, "Hooks") extend distally from a connecting tube coupled to the distal end of the control wire. Each Hook hooks onto the proximal pin on opposite sides of the clip from one another to form a connection between the control wire and the clip. The Hooks and the proximal pin form a mechanical connection between the control wire and the clip, and that link is a breakable link adapted to be broken in that the Hooks are designed such that, when the control wire retracts and subjects the Hooks to a sufficient tensile force, the connection between the Hooks and the proximal pin is broken, thereby uncoupling the control wire from the clip. The Hooks are designed to mechanically fail by fracturing (e.g., by plastic deformation that causes the Hooks to fracture—*see, e.g.*, BSC-MT139793, -849, and -857) so as to release from the proximal pin upon application of that tensile force. *See* BSC-MT139793, -849, and -857. The Hooks are intended to uncouple from the clip in this manner while the clip remains attached to the target tissue, so that the clip can remain in the patient's body while the remainder of the device is withdrawn.

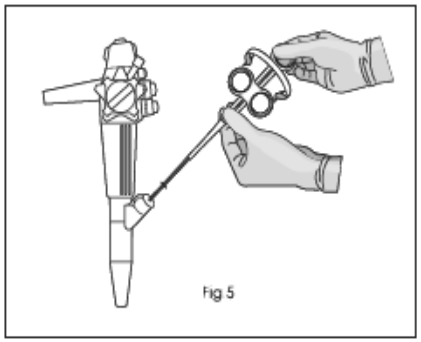
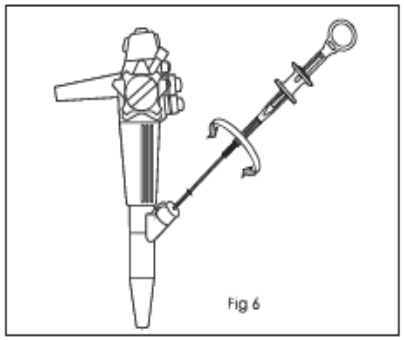
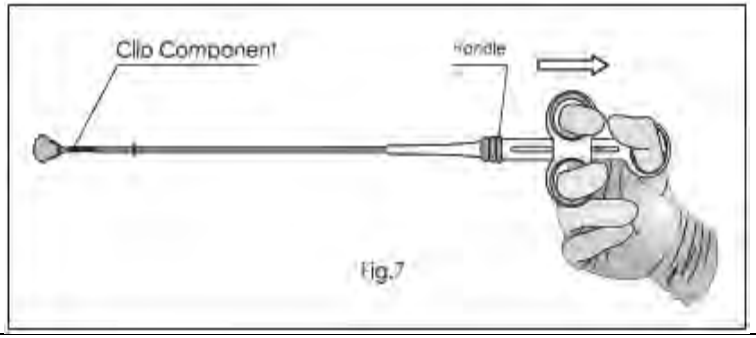
	A tensile force sufficient to cause the breakable link to break in this manner is applied when the user exerts a tensile force on the control wire and this force is opposed by a corresponding oppositely directed force via the coil shaft, the bushing, and the capsule. *See, e.g.*, Exhibit 1, at Figs. 9 and 10; MT00000093-104   For each Accused Lockado Device, a pair of C-shaped Hooks (each, a "Hook," and collectively, "Hooks") extend proximally from the clip legs. Each Hook hooks onto the proximal pin (which, for the Accused Lockado Device, is fused to the yoke coupled to the distal end of the control wire) to form a connection between the control wire and the clip. The Hooks and the proximal pin thereby form a mechanical connection between the control wire and the clip and that link is a breakable link adapted to be broken in that the Hooks are designed such that, when the control wire retracts and subjects the Hooks to a sufficient tensile force, the connection between the Hooks and the proximal pin is broken, thereby uncoupling the control wire from the clip. The Hooks are designed to mechanically fail by fracturing (e.g., by plastic deformation that causes the Hooks to fracture) so as to release from the proximal pin upon application of that tensile force. The Hooks are intended to uncouple from the clip in this manner while the clip remains attached to

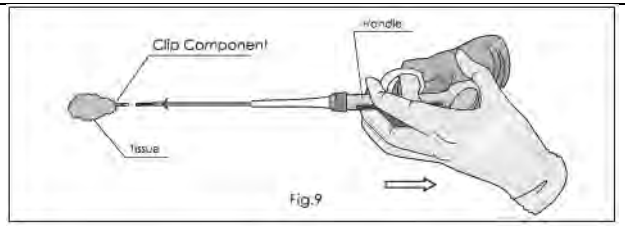
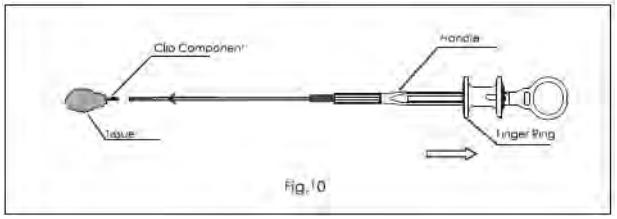
	the target tissue, so that the clip can remain in the patient's body while the remainder of the device is withdrawn. A tensile force sufficient to cause the breakable link to break in this manner is applied when the user exerts a tensile force on the control wire and this force is opposed by a corresponding oppositely directed force via the coil shaft, the bushing, and the capsule.
the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip;	The Court has construed the term "the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip" to require that "when the control wire is coupled to the clip, the control wire can be both pushed and pulled to open and close the clip legs." *See* D.I. 140. Each Accused Device includes a control wire that is coupled to the clip by way of the above-described breakable link. Application of a proximally directed force to the control wire draws the clip legs proximally within the capsule with engagement between the slots formed in the proximal portion of the clip legs and the distal pin closing the clip legs over any tissue received between the clip legs. Application of a distally directed force to the control wire opens the clip legs. As the clip legs move distally within the capsule, the distal pin—which is rigidly coupled to the distal end of the capsule—rides through the slots formed in the clip legs to force the clip legs apart from one another to open into a tissue-receiving configuration. The clip legs may be opened and closed in this manner until the endoscopist is ready to deploy the clip. *See, e.g.*, MT0000020, MT0000021. Defendants assert that the control wire is not "coupled to" the clip. They are wrong for the reasons described above. To the extent it is determined, however, that the control wire is not coupled to the clip, each Accused Device nevertheless satisfies this limitation under the doctrine of equivalents because any difference between the manner in which the control wire of the Accused Devices is connected to the clip and

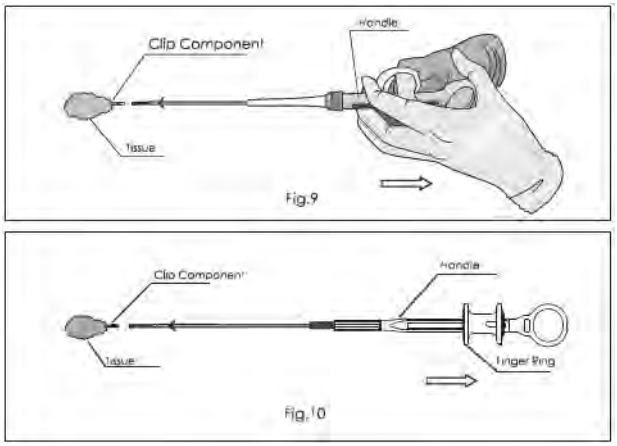
	the requirement of the claim that the control wire be "coupled to" the clip is insubstantial for purposes of the claimed invention. In particular, and among other things, the connection of the control wire to the clip via the breakable link of the Accused Devices performs substantially the same function (linking the two components together prior to deployment of the clip), in substantially the same way (linking them together via a breakable link adapted to be broken upon application of a predetermined tensile force), to achieve substantially the same result (allowing the clip to be opened and closed until the endoscopist is ready to deploy the clip, and thereafter allowing the clip to become unlinked from the control wire and remain in the body after the control wire is removed) as the control wire being "coupled to" the clip as recited in the claim.
an axially rigid sheath enclosing the control wire, the sheath able to communicate a first force opposing a second force of the control wire;	The parties have agreed that "sheath" should be given its plain and ordinary meaning. *See* D.I. 140. Each of the Accused Devices has an axially rigid sheath, which encloses the control wire and is comprised of the coil shaft, and which is able to both pushed distally through the endoscope to reach the target area within the patient's body and communicate a first force opposing a second force of the control wire. Each Accused Device also includes a bushing that is coupled to a distal end of the coil shaft, and a distal end of the bushing is received within an opening at the proximal end of the capsule. When the clip legs are drawn proximally within the capsule by a certain distance, a locking tab at a proximal end of each of the clip legs engages an internal counterbore within the capsule preventing the clip from being drawn further proximally into the capsule. At this point, additional proximally directed force applied by a user to the control wire is resisted by the axial stiffness of the coil shaft, the bushing and the capsule increasing a tensile force applied to the control wire and, consequently, to the breakable link. When this tensile force exceeds a threshold level, the breakable link is broken as the Hooks release from the proximal pin (as described above). This frees the control wire from the clip and, at the same time, the locking tabs engage the internal counterbore to prevent the clip legs from moving distally relative to the capsule, locking the clip closed over the target tissue.

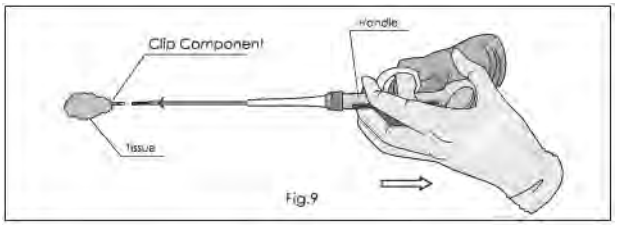
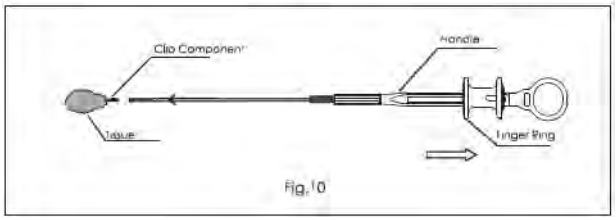
	At the same time, in the Accused Original/Buckle Devices, when the hypotube is retracted proximally upon failure of the breakable link, the hypotube engages the three-pronged spring tab, pulling it out of engagement with the holes in the capsule, freeing the clip from the proximal part of the device so that it remains in the body clipped to the target tissue. In the Accused Lockado Devices, two spring tabs in the proximal end of the capsule engage the holes at the distal end of the bushing, and upon application of a proximal force, the spring tabs deform and disengage from the holes in the bushing, which causes the capsule to separate from the bushing. In the Accused Devices, the entire proximal part of the device (including the bushing, the coil shaft, the control wire and the hypotube) is withdrawn from the body. *See, e.g.*, Exhibit 1, at Figs. 5 and 6; MT00000093-104; MT00000154.   Defendants assert that the sheath of the Accused Devices is not an "axially rigid" sheath because it allegedly is "deformable in the axial direction." Plaintiffs disagree that the sheath of the Accused Devices fails to literally satisfy this limitation. To the extent it is determined, however, that the accused sheath is not "axially rigid," each Accused Device nevertheless satisfies this limitation under the doctrine of equivalents because any difference between the sheath of the Accused Devices and the claimed "axially rigid" sheath is insubstantial for purposes of the claimed invention. In particular, and among other things, the sheath of the Accused Devices performs substantially the same function (enclosing the control wire and having

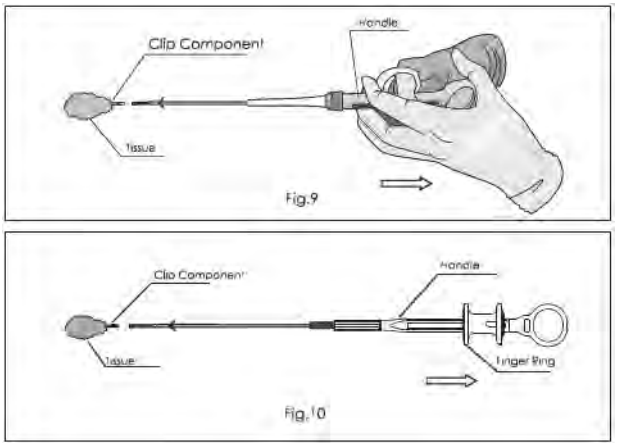
	sufficient axial rigidity to enable the device to be delivered to the target site through an endoscope and resist movement of the clip in the proximal direction when the control wire is pulled proximally), in substantially the same way (axial rigidity that resists the application of force in an axial direction) to achieve substantially the same result (reliable delivery of the device to the target site and deployment of the clip) as the claimed "axially rigid" sheath.
a handle coupled to the axially rigid sheath; and	Each of the Accused Devices includes a handle that is coupled to the proximal end of the coil shaft. *See, e.g.*, Exhibit 1, at Fig. 7; MT00000093-104.  Defendants assert, without explanation, that the handle in each of the Accused Devices is not coupled to the coil shaft. Because they do not provide any explanation, Plaintiffs are unable to further respond. To the extent the Defendants supplement their interrogatories to explain the basis for their assertion, Plaintiffs reserve the right to assert, in the alternative, that even if it is determined that Defendants are correct, the Accused Devices satisfy this limitation under the doctrine of equivalents.
an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs, to close the at least two clip legs, and to uncouple the control wire from the clip;	Each of the Accused Devices includes an actuator that is coupled to the control wire and is also coupled to and slidable with respect to the handle. As described above, application of a distally directed force to the control wire via sliding of the actuator in a distal direction vis-à-vis the handle extends the clip legs distally from the capsule so that engagement between the distal pin and the slots formed in the proximal

	portion of the clip legs pushes the clip legs apart from one another to open them into a tissue receiving configuration. Application of a proximally directed force to the control wire via the actuator (via sliding of the actuator in a proximal direction vis-à-vis the handle) draws the clip legs proximally into the capsule with engagement between the distal pin and the slots formed in the proximal portion of the clip legs drawing the clip legs together over any tissue received therebetween. Furthermore, when the clip legs have been drawn proximally into engagement with the internal counterbore of the capsule, increased proximally directed force applied to the control wire via the actuator exceeding the threshold level increases the tensile force applied to the breakable link until the link is broken uncoupling the control wire from the clip. *See, e.g.*, Exhibit 1, at Figs. 5-7, 9, 10; MT00000093-104   

	 Fig.9  Fig.10 Defendants assert that the actuator is not "coupled to" the control wire, but provide no basis for that assertion. They are wrong for the reasons described above. To the extent it is determined, however, that the actuator is not coupled to the control wire, each Accused Device nevertheless satisfies this limitation under the doctrine of equivalents because any difference between the manner in which the actuator of the Accused Devices is connected to the control wire and the requirement of the claim that the actuator be "coupled to" the control wire is insubstantial for purposes of the claimed invention. In particular, and among other things, the connection of the actuator to the control wire of the Accused Devices performs substantially the same function (connecting the two components together such that movement of the actuator causes movement of the control wire), in substantially the same way (mechanically linking them together), to achieve substantially the same result (the ability to open and close the clip legs by engaging the actuator to reversibly operate the control wire in the proximal and distal directions) as the actuator being "coupled to" the control wire as recited in the claim.
wherein when the breakable link is broken, the control wire uncouples from the clip.	For each Accused Device, when the breakable link is broken (in the manner described in detail above), the control wire uncouples from the clip.

Patent No. 7,094,245; Claim 3	**Micro-Tech Hemostasis Clip**
The medical device of claim 1, wherein:	See claim 1.
the control wire is able to be coupled to the clip by a j-hook;	For the Accused Original Devices, the control wire is able to be coupled to the clip by a J hook. The pair of J-shaped Hooks of each Accused Original Device extend distally from a connecting tube coupled to the distal end of the control wire. Each such Hook hooks onto the proximal pin on opposite sides of the clip from one another to form a connection between the control wire and the clip. *See, e.g.*, Exhibit 1, at Figs. 9 and 10.  *See, e.g.*, MT00000157. The C-shaped Hooks of the Accused Buckle and Lockado Devices are specifically designed to operate in the same manner as the J-shaped Hook of the Accused Original Device, such that to the extent the Hook of the Accused Buckle and Lockado Devices do not satisfy this limitation literally, any differences between them and the claimed "j-hook" are insubstantial for purposes of the claimed invention. In particular, and among other things, those Hooks perform substantially the same

	function (releasably coupling the control wire to the clip), in substantially the same way (via straightening in response to the application of a tensile force applied to the control wire), to achieve substantially the same result (reliable deployment of the clip). Defendants assert that the control wire is not "coupled to" the clip. They are wrong, and for each Accused Device, the control wire is coupled to the clip via the Hooks in a manner that satisfies this limitation, either literally or under the doctrine of equivalents, for the reasons described above.
the j-hook is able to be straightened by the first predetermined tensile force; and	For the Accused Original Devices, when the control wire retracts and subjects the Hooks to a first predetermined tensile force, the Hooks will straighten (by way of plastic deformation—*see, e.g.,* BSC-MT139793, -849, and -857)). *See, e.g.*, Exhibit 1, at Figs. 9 and 10; MT00000093-104.   Defendants assert, without explanation, that the "hooks in the SureClip do not straighten." Because they do not provide any explanation, and did not ask the Court to construe the term "straighten," Plaintiffs are unable to further respond, other than to assert that the ability of the Hooks, by design, to straighten (by plastic

	deformation—*see, e.g.,* BSC-MT139793, -849, and -857) so as to uncouple from the proximal pin literally satisfies this limitation. To the extent the Defendants supplement their interrogatories to explain the basis for their assertion, Plaintiffs reserve the right to assert, in the alternative, that even if it is determined that Defendants are correct, the Accused Devices satisfy this limitation under the doctrine of equivalents. Moreover, the C-shaped Hooks of the Accused Buckle and Lockado Devices are specifically designed to operate in the same manner as the J-shaped Hooks of the Accused Original Device, such that any differences between them are insubstantial, for the reasons discussed above.
when the j-hook is straightened, the control wire uncouples from the clip.	As is described in detail above, when the Hooks are straightened after being subjected to a first predetermined tensile force, the control wire uncouples from the clip. *See, e.g.*, Exhibit 1, at Figs. 9 and 10; MT00000093-104.  The C-shaped Hooks of the Accused Buckle and Lockado Devices are specifically designed to operate in the same manner as the J-shaped Hooks of the Accused Original Device, such that any differences between them are insubstantial.

Patent No. 7,094,245; Claim 7	**Micro-Tech Hemostasis Clip**
The medical device of claim 1,	See claim 1.
further comprising a lock arrangement for locking the at least two clip legs in a closed position.	The Accused Devices comprise a lock arrangement for locking the at least two clip legs in a closed position. When the clip legs are drawn proximally into the capsule by a certain distance, a locking tab at a proximal end of each of the clip legs engages an internal counterbore within the capsule preventing the clip from being drawn further proximally into the capsule. At this point, additional proximally directed force applied by a user to the control wire is resisted by the axial stiffness of the coil shaft, the bushing and the capsule increasing a tensile force applied to the control wire and, consequently, to the breakable link. When this tensile force exceeds a threshold level, the breakable link is broken as the Hooks release from the proximal pin. This frees the control wire from the clip and, at the same time, the locking tabs engage the internal counterbore to prevent the clip legs from moving distally relative to the capsule, locking the clip closed over target tissue. *See, e.g.*, MT00000149, MT00000169. Defendants assert, without explanation, that the "[t]he SureClip does not include any type of locking arrangement as described in the '245 patent." Because they do not provide any explanation, and did not ask the Court to construe the term "lock arrangement," Plaintiffs are unable to further respond, other than to assert that the locking arrangement of the Accused Devices described above literally satisfies this limitation. To the extent the Defendants supplement their interrogatories to explain the basis for their assertion, Plaintiffs reserve the right to assert, in the alternative, that even if it is determined that Defendants are correct, the Accused Devices satisfy this limitation under the doctrine of equivalents.

Patent No. 7,094,245; Claim 13	**Micro-Tech Hemostasis Clip**
The medical device of claim 1,	See claim 1.
wherein the device is disposable.	The Accused Devices are disposable. *See* Exhibit 1, at 7 ("Handle and dispose of in accordance with hospital, local and administrative laws and regulations."); MT00000093-104.

Patent No. 7,094,245; Claim 15	**Micro-Tech Hemostasis Clip**
A method of providing and using a medical device to deploy a clip for causing the hemostasis of a blood vessel, said method comprising: (i) providing a medical device comprising:	The Accused Devices are hemostasis clips for use through an endoscope. *See, e.g.*, Exhibit 1, at 1 ("The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract"); MT00000039; MT00000093-104. Under the direction and control of an endoscopist or other medical professional practicing the claimed method, the endoscopist and/or other medical staff provide the Accused Device for unpackaging and further provide the Accused Device to perform the claimed medical procedure.
a clip, wherein the clip has at least two clip legs;	*See* contentions regarding the identical limitation recited in claim 1 above. Those contentions are incorporated as if set forth at length herein.
a control wire coupled to the clip, the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs, the control wire being uncouplable from the clip;	*See* contentions regarding the "control wire" limitation recited in claim 1 above. Those contentions are incorporated as if set forth at length herein. For each Accused Device, the control wire is coupled to and uncouplable from the clip, and is reversibly operable in the manner recited by this limitation, as is described in detail above.
an axially rigid sheath enclosing the control wire, the sheath able to communicate a force opposing a force of the control wire;	*See* contentions regarding the identical limitation recited in claim 1 above. Those contentions are incorporated as if set forth at length herein.
a handle coupled to the axially rigid sheath; and	*See* contentions regarding the identical limitation recited in claim 1 above. Those contentions are incorporated as if set forth at length herein.
an actuator coupled to the control wire, the control wire engageable by the actuator to open the at least two clip legs and to close	*See* contentions regarding the identical limitation recited in claim 1 above. Those contentions are incorporated as if set forth at length herein.

the at least two clip legs and to uncouple the control wire from the clip;	
(ii) advancing the medical device so that the clip is located at the desired deployment location; and	During operation, the Accused Devices are inserted into the body and advanced from the insertion point, through the body, until the clip reaches the portion of target tissue to be grasped. *See, e.g.*, Exhibit 1, at 5-6 ("Advance the device until contact is made with the targeted site. . . . If the clip is not in its desired position, the clip may be re-opened and repositioned."); MT00000093-104.
(iii) moving the actuator to close the clip legs, and optionally to reopen and reclose the clip legs, and to uncouple the clip from the control wire;	A proximally directed force applied by the actuator to the control wire forces the clip legs closed and a distally directed force applied by the actuator to the control wire forces the clip legs open. The clip legs are free to transition between the open and closed configurations until the clip legs are drawn a certain distance proximally into the capsule and a locking tab at the proximal end of each clip leg engages the internal counterbore within the capsule. At this point, additional proximally directed force applied to the control wire is resisted by the axial stiffness of the coil shaft, the bushing and the capsule increasing a tensile force applied to the connection between the Hooks and the proximal pin until a tensile force sufficient to cause the Hooks to mechanically fail by fracturing (e.g., by plastic deformation that causes the Hooks to fracture—*see, e.g.,* BSC-MT139793, -849, and -857) and release the connection between the control wire and the clip is achieved. *See, e.g.*, Exhibit 1, at 6 ("If the clip is not in its desired position, the clip may be re-opened and repositioned. . . . To deploy the clip, continue pulling back the finger rings beyond the tactile resistance point. You will hear an audible snap when the clip component detaches."); MT00000093-104.

wherein the control wire is adapted to be coupled to the clip by a breakable link; wherein the breakable link is adapted to be broken by a first predetermined tensile force applied by the control wire; and wherein when the breakable link is broken, the control wire uncouples from the clip.	*See* claim 1 above. The Court has construed "breakable link . . . adapted to be broken" as "a component of the device designed to mechanically fail by fracturing at a predetermined tensile load." D.I. 140 For each Accused Device, the Hooks and the proximal pin form "a breakable link" that couples the control wire to the clip and "is adapted to be broken by a first predetermined tensile force applied by the control wire" for the reasons set forth above with respect to claim 1. As also described above with respect to claim 1, when that link is broken, the control wire uncouples from the clip.

EXHIBIT 1

Micro-Tech USA SureClip™ Repositionable Hemostasis Clip Instructions for Use

MICRO-TECH ENDOSCOPY

SureClip™
SureClip™ PLUS
SureClip™ MINI
Repositionable Hemostasis Clip

Instructions for Use

Micro-Tech (Nanjing) Co., Ltd.

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:
endoscopic marking,
hemostasis for
(a) mucosal / sub-mucosal defects < 3cm,
(b) bleeding ulcers,
(c) polyps < 1.5cm in diameter,
(d) diverticula in the colon,
As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively

CONTRAINDICATIONS

1. Mucosal / submucosal defects greater than 3cm;
2. Polyps greater than 1.5 cm in diameter;
3. The patient with poor general condition who cannot tolerate endoscopy;
4. The patient has narrow upper digestive tract where endoscope cannot pass through;
5. The patient has serious coagulation disorders and hemorrhagic diseases;
6. The patient is allergic to the device and the drugs used in the operation;
7. The patient who is not suitable to use the product per the diagnosis;
8. The patient or the families are uncooperative.

POTENTIAL COMPLICATIONS

1. Inflammation of tissue, perforation, bleeding or mucosal damage for the patient;
2. Infection, septicemia, etc;
3. Complications which are not currently known or observed may be present.

WARNINGS

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. The product is only intended for adult populations.
4. The clips are stainless steel. Do not use them on a patient who is severely allergic to metals. This device is not made with natural rubber latex.
5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance takes place.
7. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
8. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.
9. Do not use this instrument when hemostasis cannot be verified visually within the endoscopic field of view.
10. Do not operate the spiral tube and clip with excessive force as this may cause damage to the device.
11. It may be difficult to stop bleeding depending on the situation. Prepare more than one hemostasis device. Some devices may be used together for best result.
12. Bleeding may occur on the clipping site, depending on the local condition. Check the patient for any re-bleeding after the procedure as appropriate.
13. Always observe the endoscopic image during operation. If the clip deploys prematurely, remove it with foreign body retrieval forceps.
14. Limited studies indicate that lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with forward-viewing endoscope.
15. Limited studies indicate that the treatment of esophageal varices may require

clipping in combination with a sclerosing agent.

16. Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
17. Limited studies have shown that the number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type and patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.
18. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

【 Product Name 】SureClip™ Repositionable Hemostasis Clip
【 Packaging 】Packed in pouch
【 Production Date 】 See packaging
【 Sterilization 】 Sterilized by EO (ethylene oxide) gas
【 Shelf Life】 3 years
【 Compatible Working Channel 】≥ φ2.8mm

STRUCTURE

SureClip™ Repositionable Hemostasis Clip includes a clip component, distal end of spring tube, proximal end of spring tube and handle component (Fig.1 and Fig.2).

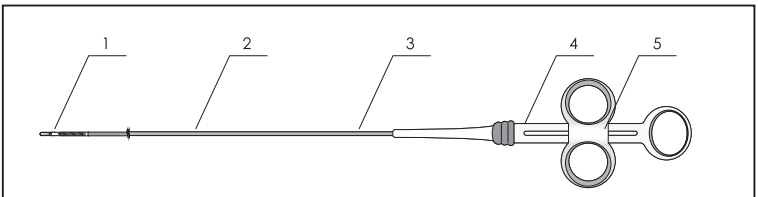


Fig.1 Schematic diagram of SureClip™ Repositionable Hemostasis Clip (three-ring)

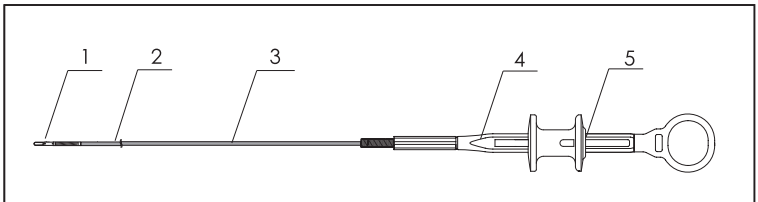


Fig.2 Schematic diagram of SureClip™ Repositionable Hemostasis Clip (single-ring)

1. Clip component 2. Distal end of spring tube 3. Proximal end of spring tube
4. Handle component 5. Finger Ring

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged.
4. Verify the expiration date. Do not use if expired.
5. Open the package carefully using acceptable aseptic technique.
6. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
7. Before use, check the clip and the spring tube to ensure that there are no sharp edges. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
8. Prior to use, remove the protective sleeve and gently open and close the device to confirm it is functioning.

NOTE: Excessive force may result in the clip deploying before use.

NOTE: Hyper-extending the finger rings away from thumb ring should be avoided. Excessive force may damage the device and affect performance.

INSTRUCTIONS FOR USE

1. The device is compatible with an endoscope channel of 2.8mm or larger.
2. Carefully insert device into endoscope channel, ensuring that the clip is in the closed position (See Fig.3 and Fig 4).

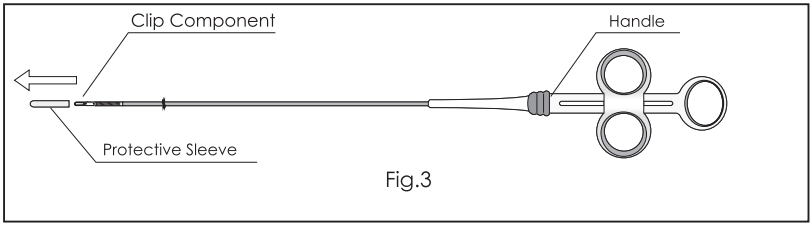


Fig.3

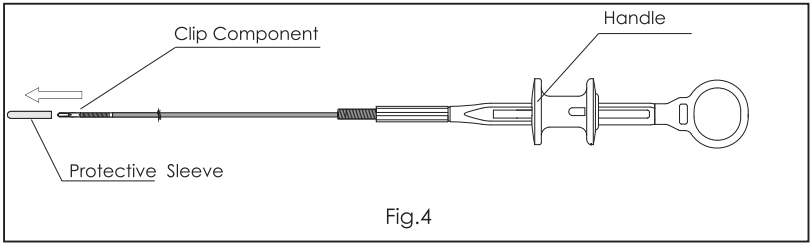


Fig.4

3. Advance the clip in small incremental movements towards the target site. Once in the instrument channel, there is no need to apply closure pressure on the handle.

NOTE: Applying excessive closure pressure to the handle during insertion, may result in detachment of the clip.

NOTE: Endoscope should remain as straight as possible when inserting the device.

NOTE: When introducing the device, in an endoscope in a tortuous position, straightening the endoscope may improve passage and exposure of the clip. With the clip in place, carefully reposition the endoscope for treatment.

4. When in endoscopic view, gently open the clip by gently sliding the finger ring forward.
5. Clip can be rotated clockwise or counter-clockwise by slowly turning the handle component until desired position is achieved. During rotation, the handle component and finger ring should be allowed to rotate. (See Fig.5 and Fig.6)

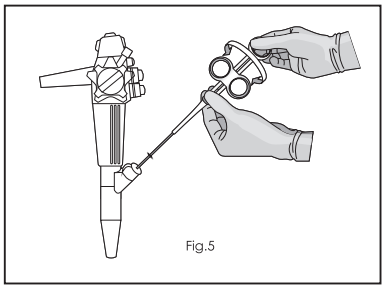


Fig.5

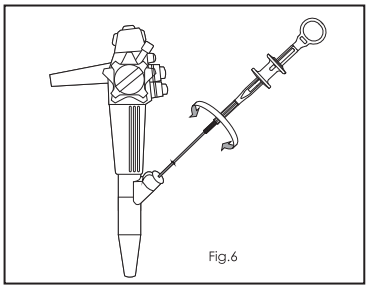


Fig.6

6. Advance the device until contact is made with the targeted site.
7. When satisfied with clip positioning, close the clip onto the tissue by pulling the finger rings back until tactile resistance is felt in the handle. The clip position may now be assessed prior to deployment. (See Fig.7 and Fig.8)

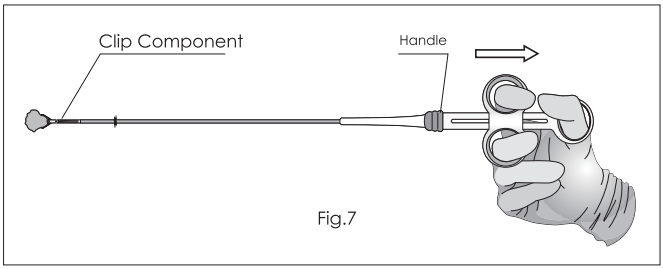


Fig.7

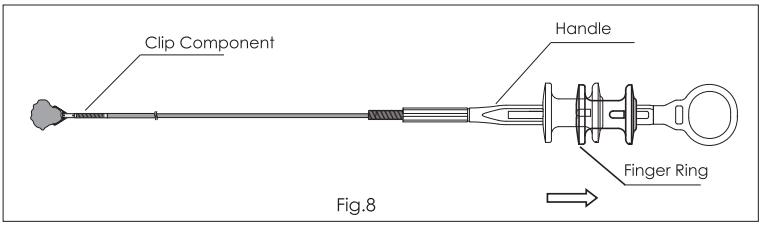


Fig.8

If the clip is not in its desired position, the clip may be re-opened and repositioned.

NOTE: Do not continue to pulling back the finger rings beyond the tactile resistance until you are ready to deploy the clip, otherwise you may not be able to re-open the clip. If you hear or feel a click, the clip cannot be re-opened.

8. To deploy the clip, continue pulling back the finger rings beyond the tactile resistance point .You will hear an audible snap when the clip component detaches. (See Fig.9 and Fig.10).

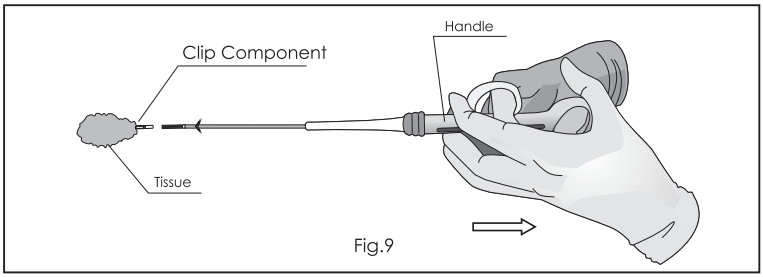


Fig.9

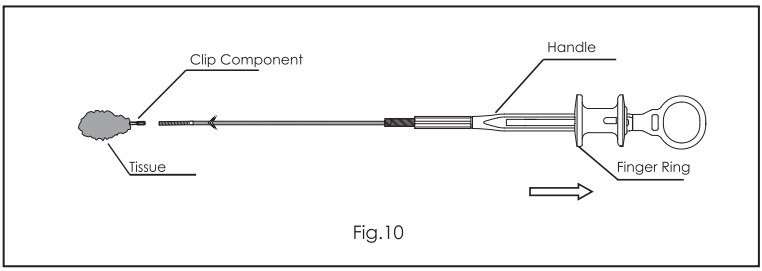


Fig.10

NOTE: If the clip did not immediately detach from the catheter, then apply gently movement of the catheter or endoscope to unseat the clip.

NOTE: Do not advance the finger rings after deployment as this may damage the device.

9. Remove sheath from endoscope by slowly retracting the device.

NOTE: Endoscope should remain as straight as possible when withdrawing the device.

MR Safety Information

MR Conditional

Non-clinical testing has demonstrated that the SureClip™ Repositionable Hemostasis Clip is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3T only
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SureClip™ Repositionable Hemostasis Clip is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 25mm from the SureClip™ Repositionable Hemostasis Clip when imaged with a gradient echo or spin echo pulse sequence in a 3 Tesla MRI system.

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 3 years.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

Limited Warranty and Disclaimers:

1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA's part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.

2. Disclaimer and Release. **THE WARRANTIES, OBLIGATIONS, AND LIABILITIES OF Micro-Tech USA AS SET FORTH HEREIN ARE EXCLUSIVE. BUYER HEREBY WAIVES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE PRODUCTS AND ANY OTHER GOODS OR SERVICES DELIVERED BY BUYER, INCLUDING, BUT NOT LIMITED TO: (1) ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND (2) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.**

3. Implied Warranties. The purchase of products may be subject to laws in the territories applicable to the sale of the products by Micro-Tech USA to Buyer that impose implied warranties, conditions, or obligations that cannot be excluded, restricted, or modified, or can only be excluded, restricted, or modified to a limited extent. The provisions of Paragraphs 2 and 4 shall apply to the greatest extent allowed by such laws.

4. Limitation of Liability. **EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, Micro-Tech USA'S LIABILITY UNDER THIS WARRANTY IS LIMITED TO: (a) THE REPLACEMENT OF THE PRODUCTS OR THE RE-SUPPLY OF EQUIVALENT PRODUCTS; (b) THE REPAIR OF THE PRODUCTS OR PAYMENT OF THE COST OF REPAIRING THE PRODUCTS; or (c) PAYMENT OF THE COST OF REPLACING THE PRODUCTS OR ACQUIRING EQUIVALENT PRODUCTS. MICRO-TECH USA SHALL HAVE NO OBLIGATION OR LIABILITY, WHETHER ARISING IN CONTRACT (INCLUDING WARRANTY), TORT (INCLUDING ACTIVE, PASSIVE, OR IMPUTED NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY) OR OTHERWISE, FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE,**

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EXHIBIT 2

Micro-Tech USA SureClip™ Hemostasis Clip Data Sheet

MICRO-TECH™ ENDOSCOPY

CLIP WITH CONFIDENCE
THE SURECLIP®

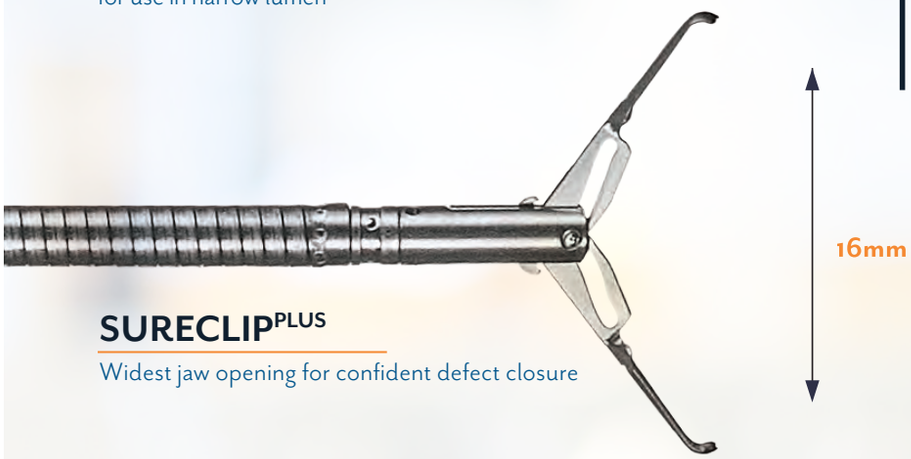
Clips need to be reliable. They need to be accurate. They need to allow you the flexibility to reposition or rotate as much as is required to deliver better outcomes.

Accurate positioning prior to deployment can reduce both procedure time and the number of clips needed to achieve hemostasis. SureClip achieves this by design delivering outstanding repositionability and reliable rotation prior to deployment, in various scope positions. SureClip's short stem aids placement in narrow lumen and improves visibility.

The proprietary clip design provides reliable deployment, may improve retention, and offers a choice of jaw sizes.

SURECLIP

Shortest stem, approximately 5mm, for use in narrow lumen



SURECLIP^PLUS

Widest jaw opening for confident defect closure

NEW PRODUCT!

SURECLIP^MINI

Lowest jaw profile for unobstructed view during placement

NEVER COMPROMISE **ON QUALITY**

DRAMATICALLY IMPROVE YOUR **BOTTOM LINE**

THROW AWAY CONTRACTS **FOREVER**

RELIABLE SUPPLY **PARTNERSHIP**

KEY BENEFITS

REPOSITIONING

SureClip's unique design permits opening and closing the jaw prior to deployment. Being able to reposition a clip may help improve placement accuracy. Fenestrations on the SureClip^{PLUS} and SureClip^{MINI} accommodate tissue and may enhance retention.

RELIABLE ROTATION

SureClip can be rotated, helping to provide the correct orientation for tissue approximation or defect closure. The rotation handle on the SureClip improves performance and enhances the user experience.

SHORT STEM

A shorter stem makes the clip less obtrusive, improving visualization of the target area, particularly when multiple clips are placed in close proximity.

SPECIFICATIONS

SURECLIP^{MINI} LOWEST PROFILE

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30415	132-5180	8	Max 2.6	235	2.8	2/Box
RC30411	132-5187	8	Max 2.6	235	2.8	10/Box

SURECLIP SHORTEST STEM

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30445	132-5724	11	Max 2.6	235	2.8	2/Box
RC30441	132-5723	11	Max 2.6	235	2.8	10/Box

SURECLIP^{PLUS} WIDEST JAW OPENING

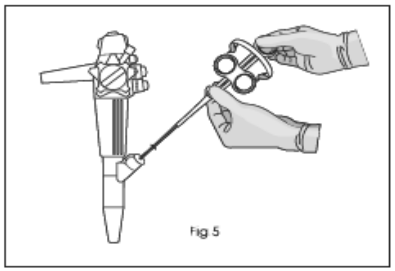
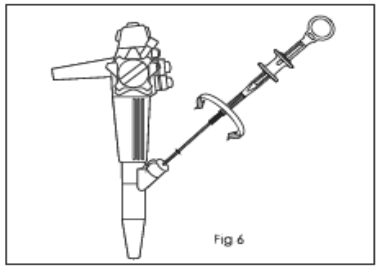
Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30385	128-5657	16	Max 2.6	235	2.8	2/Box
RC30381	128-5655	16	Max 2.6	235	2.8	10/Box

*Jaws may not open to maximum reach until placed in contact with tissue

CAN'T FIND IT?

Additional items may be available. Contact us if you can't find what you need.

EXHIBIT B

Patent No. 8,974,371; Claim 1[1]	**Micro-Tech Hemostasis Clip**
An apparatus for applying clips to tissue, comprising:	Each of the Accused Devices is a hemostasis clip for use through an endoscope to apply clips to tissue, as described more fully below. *See, e.g.*, Micro-Tech USA SureClip™ Repositionable Hemostasis Clip Instructions for Use (Exhibit 1), at 1 ("The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract"); MT00000039; MT00000093-104.
a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped;	The Court has construed "sheath" as "one or more components of the delivery device that enclose the control wire." *See* D.I. 140. Each Accused Device includes a flexible sheath comprised of a coil shaft. The coil shaft extends from a proximal end to a distal end and a control wire passes freely through the coil shaft. Thus, the coil shaft forms a sheath over the control wire. Further, the coil shaft must be flexible enough such that, in operation, it is able to pass through the bends of the endoscope and navigate through the body until the distal end of the device reaches the target tissue. *See, e.g.*, Exhibit 1, at Figs. 5, 6, 9, and 10; MT00000093-104; MT00000154.  

[1] Claim 1 of the '371 Patent is not independently asserted. However it is presented in these charts because asserted dependent claims 8 and 9 of the '371 Patent depend therefrom.BG

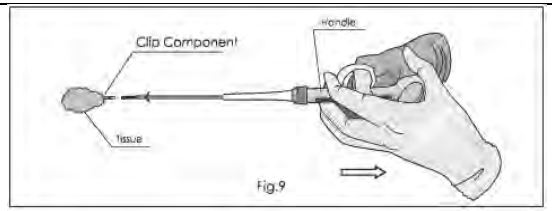


Fig.9

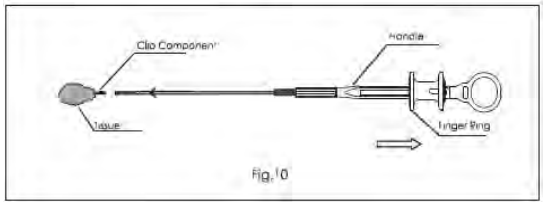
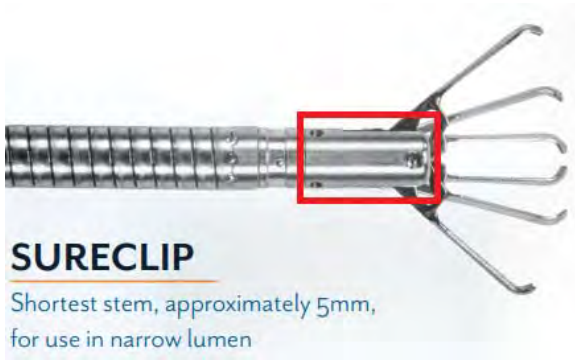


Fig.10

Defendants assert that the sheath of the Accused Devices "does not 'in an operative configuration' extend to 'a target portion of tissue to be clipped'" and does not "extend into the living body and to the tissue," and thus does not literally infringe this limitation. Plaintiffs disagree that the sheath of the Accused Devices fails to literally satisfy this limitation, as the device is designed to have the recited feature.

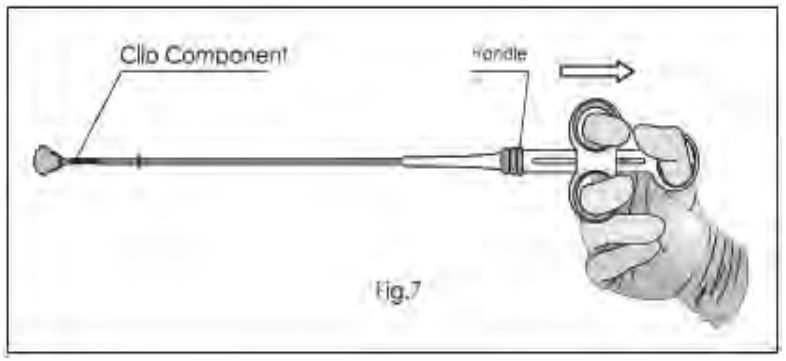
To the extent it is determined that the sheath of the Accused Devices does not " in an operative configuration, extend[] … to a target portion of tissue to be clipped" because, in operation, it does not touch the tissue to be clipped (an assertion that Defendants appear to make and with which Plaintiffs disagree), then the Accused Devices nevertheless satisfy this limitation under the doctrine of equivalents because the difference between a clip device in which the sheath, in operation, actually touches the tissue to be clipped and one that, like the Accused Devices, extends into the body and to the tissue without touching it, is insubstantial for purposes of the claimed invention. Among other things, the sheath of the Accused Devices performs substantially the same function (it acts as a housing for the control wire as the clip is inserted into the patients' body and delivered to the target site, and is thereafter withdrawn), in substantially the same way (by enclosing the control wire as it extends into the body and to the tissue to be clipped), to achieve substantially the same result (safe and reliable delivery of the clip to the target tissue), as the claimed sheath.

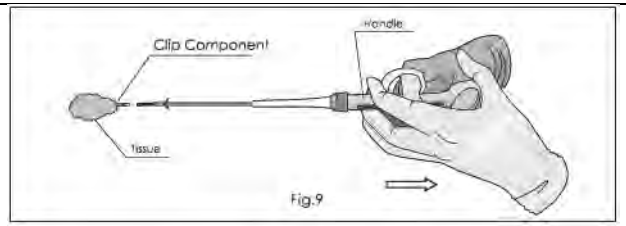
	Moreover, to the extent it is determined that the Accused Devices do not satisfy this limitation at the time that Defendants make and sell them, they do satisfy this limitation when used by physicians to perform endoscopic procedures. Defendants actively encourage physicians to use, and specifically intend them to use, the Accused Devices at a time when the Accused Devices do satisfy this limitation (as evidenced, for example and without limitation, by the Instructions For Use of the Accused Devices), and thus induce direct infringement by the physicians.
a capsule extending from a proximal to a distal end and having an opening formed in a proximal end thereof;	The Accused Devices each include a capsule that extends from a proximal end to a distal end. An opening at the proximal end of the capsule receives the distal end of the bushing. *See, e.g.*, Micro-Tech USA SureClip™ Hemostasis Clip Data Sheet (Exhibit 2), at 1; MT00000166. 
a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween;	The Court has construed "clip assembly provided in the capsule" as "an assembly having a clip, i.e., a multi-legged grasping device, provided in the capsule." *See* D.I. 140. The parties have agreed that "closed configuration" should be construed as "the configuration of the clip assembly when its clip arms are closed." *See* D.I. 140. For the Accused Original/Buckle Devices, two clip arms (that together comprise a multi-legged grasping device) are coupled together by a distal pin and a proximal pin, and can be locked in position upon deployment by a tab on the proximal arms and an internal counterbore within the capsule, all of which together form a clip assembly. For the

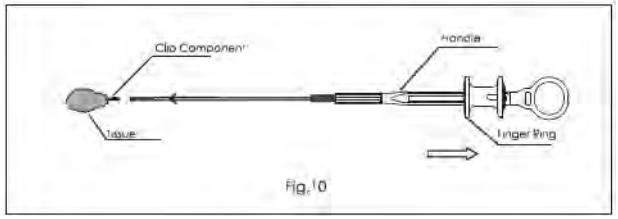
	Accused Lockado Devices, two clip arms (that together comprise a multi-legged grasping device) are coupled together by a distal pin, and can be locked in position upon deployment by a tab on the proximal arms and an internal counterbore within the capsule, all of which together form a clip assembly. For each Accused Device, the clip assembly (including the proximal portion of the clip arms) is provided within the capsule. For the Accused Devices, when the clip is inserted into the body, the clip arms are in a closed configuration. Application of a distally directed force to the control wire opens the clip arms. As the clip arms move distally within the capsule, the distal pin—which is rigidly coupled to the distal end of the capsule—rides through the slots formed in the proximal section of the clip arms to force the clip arms apart from one another to open them into a tissue-receiving configuration. Application of a proximally directed force to the control wire draws the clip arms proximally within the capsule with engagement between the distal pin and the slots formed in the proximal section of the clip arms drawing the clip arms together over any tissue received therebetween. *See, e.g.*, Exhibit 2, at 1. Such movement is reversibly operable prior to uncoupling. *See, e.g.*, *id.*, at 2 ("SureClip's unique design permits opening and closing the jaw prior to deployment."); MT00000020; MT00000021. 
a bushing extending between a proximal end coupled to the sheath and a distal end releasably coupled to	The Court has construed "coupled to the sheath" as "linked together, connected, or joined, but not slidable within the sheath." *See* D.I. 140.

the capsule via a tab on the distal end of the bushing engaging the opening of the capsule; and	Each Accused Device also includes a bushing, the proximal end of which is coupled to the distal end of the coil shaft. The bushing includes a reduced diameter section on its distal end. Each Accused Original/Buckle Device further includes a three-pronged spring tab, with each prong of the three-pronged spring tab configured to protrude out of an opening along the circumference of the reduced diameter portion of the bushing. The proximal end of the capsule receives the reduced diameter portion of the bushing and a connection is formed when the prongs of the spring further engage holes located near the proximal end of the capsule. This connection is released when the hypotube is retracted proximally upon failure of the J-shaped hooks (Original) / C-shaped hooks (Buckle) and engages the three-pronged spring tab, causing the prongs of the spring to be pulled out of engagement with the holes located at the proximal end of the capsule, freeing the capsule and the clip from the remainder of the device so that the clip remains in the body clipped to the target tissue. *See, e.g.*, MT00000166. In this manner, the bushing is releasably coupled to the capsule via the tab (reduced diameter portion) on the distal end of the bushing engaging the opening in the proximal end of the capsule. Each Accused Lockado Device further includes two spring tabs in the proximal end of the capsule. Each spring tab is configured to protrude out of an opening along the circumference of the reduced diameter portion of the bushing. The proximal end of the capsule receives the reduced diameter portion of the bushing and a connection is formed when the two spring tabs in the proximal end of the capsule engage the holes at the distal end of the bushing. Upon application of a sufficient proximal force on the control wire, the spring tabs disengage from the holes in the bushing, which causes the capsule to separate from the bushing. In this manner, the bushing is releasably coupled to the capsule via the tab (reduced diameter portion) on the distal end of the bushing engaging the opening in the proximal end of the capsule. Defendants assert, without explanation, that the bushing is not "releasably coupled" to the capsule. Because they do not provide any explanation, Plaintiffs are unable to further respond. To the extent the Defendants supplement their interrogatories to explain the basis for their assertion, Plaintiffs reserve the right to assert, in the alternative, that even if

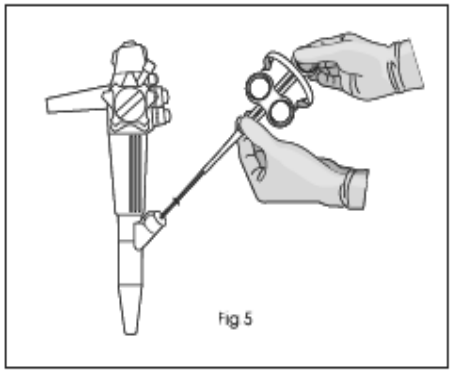
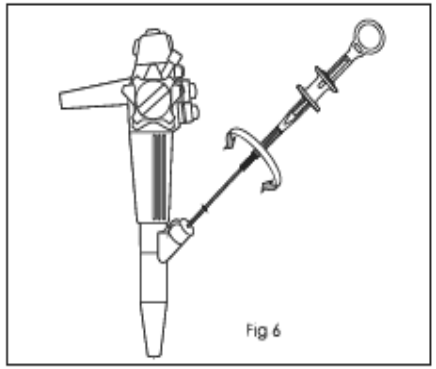
	it is determined that Defendants are correct, the Accused Devices satisfy this limitation under the doctrine of equivalents. The bushing of the Accused Devices is not slidable within the sheath. To the contrary, the outer diameter of the bushing is larger than the opening at the distal end of the sheath, such that it is not possible to slide the bushing within the sheath. Even if it were found that the bushing of the Accused Devices does not literally satisfy this limitation because it is somehow slidable within the sheath for some unexplained reason, then those Devices would nevertheless still satisfy this limitation under the doctrine of equivalents, in that any difference between the bushing of the Accused Devices and the claimed bushing as construed by Defendants is insubstantial for purposes of the claimed invention. In particular, and among other things, the bushing of the Accused Devices performs substantially the same function (providing a releasable connection between the sheath and the capsule), in substantially the same way (having a proximal end that is coupled to the sheath and a distal end that engages an opening in the proximal end of the capsule and is releasably coupled to the capsule) to achieve substantially the same result (reliable delivery of the capsule to the desired location and release of the clip upon deployment) as the claimed bushing.
a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied thereto to move the clip assembly between the insertion and expanded configurations.	The Court has construed "control member" as a "wire or other force transmission member." *See* D.I. 140. For each Accused Original/Buckle Device, the control wire, the connecting tube, the hypotube, and a pair of J-shaped (original)/C-shaped (buckle) hooks (each, a "Hook," and collectively, "Hooks") coupled to the distal end of the control wire form a control member. Each Hook hooks onto the proximal pin on opposite sides of the clip from one another to form a mechanical connection between the control wire and the clip. For each Accused Lockado Device, the control wire, the connecting tube, the yoke coupled to the distal end of the control wire, and the proximal pin fused to the yoke, form a control member. The proximal pin engages the C-shaped hooks (each, a "Hook," and collectively, "Hooks") on the proximal end of the clip arms to form a mechanical connection between the control wire and the clip.

	Application of a proximally directed force to the control wire draws the clip arms proximally within the capsule. When the clip arms are moved a certain distance proximally within the capsule, locking tabs located at the proximal end of each clip arm engage the internal counterbore within the capsule preventing the clip arms from traveling further proximally within the capsule. At this point, additional proximal forces applied to the control wire increases a tensile force applied to the control wire and to the connection between the Hooks and the proximal pin. When this tensile force reaches a level sufficient to uncouple the Hooks, the connection between the control wire and the clip releases, thereby uncoupling the control member from the clip assembly. The tensile force results from proximally directed force applied to the control wire, which is opposed by a corresponding oppositely directed force via the coil shaft, the bushing and the capsule. When the clip is inserted, the clip arms are in a closed configuration. Application of a distally directed force to the control wire advances the connection between the Hooks and the proximal pin to extend the clip arms distally out of the capsule and forcing the clips arms to transition from a closed configuration to the open configuration. When the clip arms are in an open configuration, application of a proximally directed force to the control wire retracts the connection between the Hooks and the proximal pin proximally within the capsule, forcing the clip arms to transition to the closed configuration. *See, e.g.*, Exhibit 1, at Figs. 7, 9, and 10; MT00000093-104. The clip arms may be repeatedly opened and closed in this manner until the endoscopist is ready to deploy the clip. 


Handle
Clip Component
Tissue
Fig.9


Handle
Clip Component
Tissue
Finger Ring
Fig.10

Patent No. 8,974,371; Claim 8	**Micro-Tech Hemostasis Clip**
The apparatus of claim 1,	See claim 1.
wherein the proximal end of the capsule comprises a keyed portion aligning the capsule in a desired rotational orientation with respect to the bushing.	The proximal end of the capsule of each of the Accused Devices comprises a keyed portion aligning the capsule in a desired rotational orientation with respect to the bushing. In each of the Accused Devices, the capsule is aligned in a desired rotational orientation with respect to the bushing by way of the holes located in the proximal end of the capsule (the keyed portion of the capsule), which receive the ends of spring tabs that also pass through corresponding holes in the bushing (the three-pronged spring tab described above for the Accused Original/Buckle Devices, and the spring tabs described above for the Accused Lockado Devices). *See, e.g.*, Exhibit 2, at 1.  *See also, e.g.*, MT0000020, MT0000021; MT00000166. As a result, a user can rotate the clip "clockwise or counter-clockwise by slowly turning the handle component until desired position is achieved." *See, e.g.*, Exhibit 1, at Figs. 5 and 6; MT00000093-104.

	 Fig 5  Fig 6

Patent No. 8,974,371; Claim 9	**Micro-Tech Hemostasis Clip**
The apparatus of claim 8,	See claim 8.
wherein the distal end of the bushing comprises a feature configured to mate with the keyed portion of the capsule.	The distal end of the bushing in each of the Accused Devices comprises a feature configured to mate with the keyed portion of the capsule. As is described above, the distal end of the bushing in each Accused Device includes holes that mate with the corresponding holes in the proximal end of the capsule.

EXHIBIT 1

Micro-Tech USA SureClip™ Repositionable Hemostasis Clip Instructions for Use

MICRO-TECH ENDOSCOPY

SureClip™
SureClip™ PLUS
SureClip™ MINI
Repositionable Hemostasis Clip

Instructions for Use

Micro-Tech (Nanjing) Co., Ltd.

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:
endoscopic marking,
hemostasis for
(a) mucosal / sub-mucosal defects < 3cm,
(b) bleeding ulcers,
(c) polyps < 1.5cm in diameter,
(d) diverticula in the colon,
As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively

CONTRAINDICATIONS

1. Mucosal / submucosal defects greater than 3cm;
2. Polyps greater than 1.5 cm in diameter;
3. The patient with poor general condition who cannot tolerate endoscopy;
4. The patient has narrow upper digestive tract where endoscope cannot pass through;
5. The patient has serious coagulation disorders and hemorrhagic diseases;
6. The patient is allergic to the device and the drugs used in the operation;
7. The patient who is not suitable to use the product per the diagnosis;
8. The patient or the families are uncooperative.

POTENTIAL COMPLICATIONS

1. Inflammation of tissue, perforation, bleeding or mucosal damage for the patient;
2. Infection, septicemia, etc;
3. Complications which are not currently known or observed may be present.

WARNINGS

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. The product is only intended for adult populations.
4. The clips are stainless steel. Do not use them on a patient who is severely allergic to metals. This device is not made with natural rubber latex.
5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance takes place.
7. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
8. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.
9. Do not use this instrument when hemostasis cannot be verified visually within the endoscopic field of view.
10. Do not operate the spiral tube and clip with excessive force as this may cause damage to the device.
11. It may be difficult to stop bleeding depending on the situation. Prepare more than one hemostasis device. Some devices may be used together for best result.
12. Bleeding may occur on the clipping site, depending on the local condition. Check the patient for any re-bleeding after the procedure as appropriate.
13. Always observe the endoscopic image during operation. If the clip deploys prematurely, remove it with foreign body retrieval forceps.
14. Limited studies indicate that lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with forward-viewing endoscope.
15. Limited studies indicate that the treatment of esophageal varices may require

clipping in combination with a sclerosing agent.

16. Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
17. Limited studies have shown that the number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type and patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.
18. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

【 Product Name 】SureClip™ Repositionable Hemostasis Clip
【 Packaging 】Packed in pouch
【 Production Date 】 See packaging
【 Sterilization 】 Sterilized by EO (ethylene oxide) gas
【 Shelf Life】 3 years
【 Compatible Working Channel 】≥ φ2.8mm

STRUCTURE

SureClip™ Repositionable Hemostasis Clip includes a clip component, distal end of spring tube, proximal end of spring tube and handle component (Fig.1 and Fig.2).

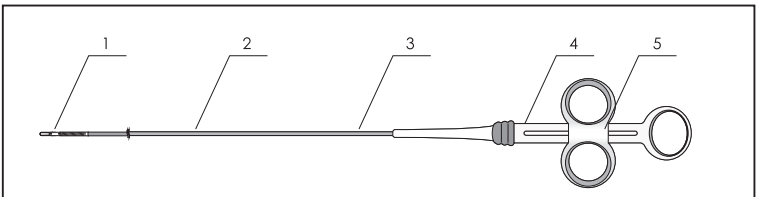


Fig.1 Schematic diagram of SureClip™ Repositionable Hemostasis Clip (three-ring)

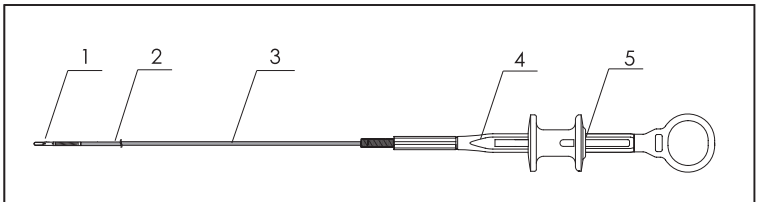


Fig.2 Schematic diagram of SureClip™ Repositionable Hemostasis Clip (single-ring)

1. Clip component 2. Distal end of spring tube 3. Proximal end of spring tube
4. Handle component 5. Finger Ring

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged.
4. Verify the expiration date. Do not use if expired.
5. Open the package carefully using acceptable aseptic technique.
6. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
7. Before use, check the clip and the spring tube to ensure that there are no sharp edges. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
8. Prior to use, remove the protective sleeve and gently open and close the device to confirm it is functioning.

NOTE: Excessive force may result in the clip deploying before use.

NOTE: Hyper-extending the finger rings away from thumb ring should be avoided. Excessive force may damage the device and affect performance.

INSTRUCTIONS FOR USE

1. The device is compatible with an endoscope channel of 2.8mm or larger.
2. Carefully insert device into endoscope channel, ensuring that the clip is in the closed position (See Fig.3 and Fig 4).

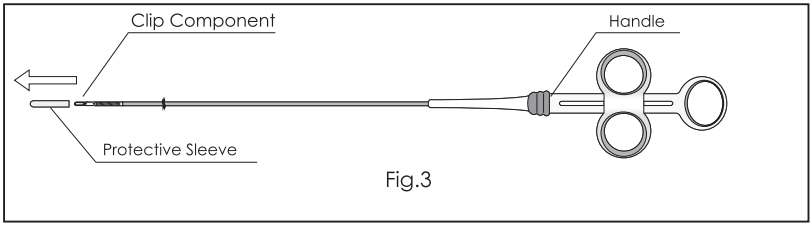


Fig.3

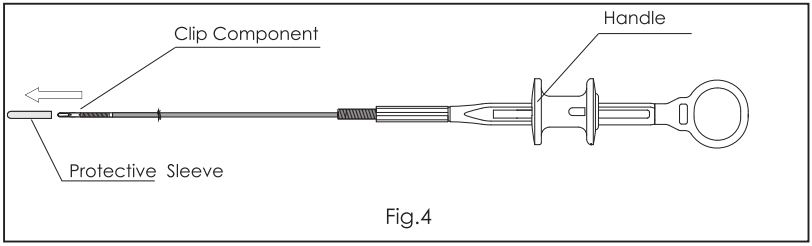


Fig.4

3. Advance the clip in small incremental movements towards the target site. Once in the instrument channel, there is no need to apply closure pressure on the handle.

NOTE: Applying excessive closure pressure to the handle during insertion, may result in detachment of the clip.

NOTE: Endoscope should remain as straight as possible when inserting the device.

NOTE: When introducing the device, in an endoscope in a tortuous position, straightening the endoscope may improve passage and exposure of the clip. With the clip in place, carefully reposition the endoscope for treatment.

4. When in endoscopic view, gently open the clip by gently sliding the finger ring forward.
5. Clip can be rotated clockwise or counter-clockwise by slowly turning the handle component until desired position is achieved. During rotation, the handle component and finger ring should be allowed to rotate. (See Fig.5 and Fig.6)

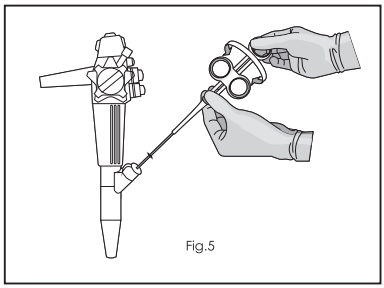


Fig.5

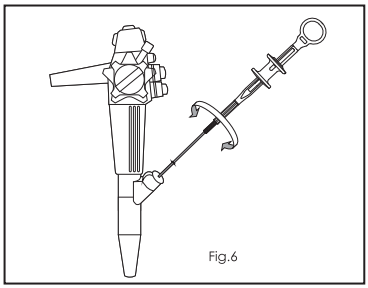


Fig.6

6. Advance the device until contact is made with the targeted site.
7. When satisfied with clip positioning, close the clip onto the tissue by pulling the finger rings back until tactile resistance is felt in the handle. The clip position may now be assessed prior to deployment. (See Fig.7 and Fig.8)

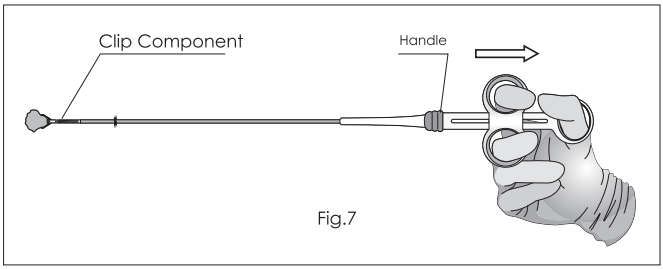


Fig.7

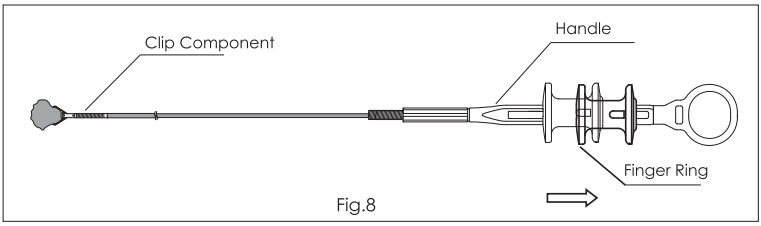


Fig.8

If the clip is not in its desired position, the clip may be re-opened and repositioned.

NOTE: Do not continue to pulling back the finger rings beyond the tactile resistance until you are ready to deploy the clip, otherwise you may not be able to re-open the clip. If you hear or feel a click, the clip cannot be re-opened.

8. To deploy the clip, continue pulling back the finger rings beyond the tactile resistance point .You will hear an audible snap when the clip component detaches. (See Fig.9 and Fig.10).

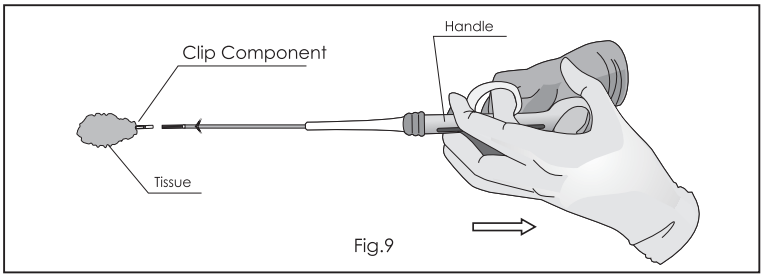


Fig.9

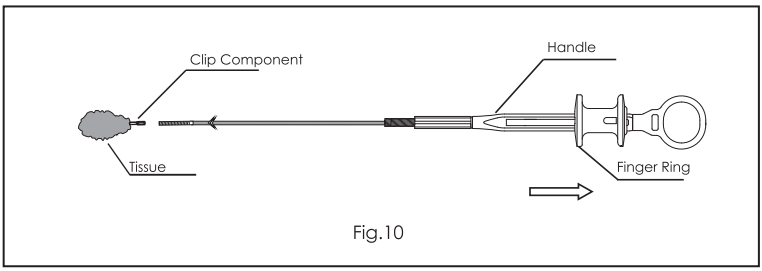


Fig.10

NOTE: If the clip did not immediately detach from the catheter, then apply gently movement of the catheter or endoscope to unseat the clip.

NOTE: Do not advance the finger rings after deployment as this may damage the device.

9. Remove sheath from endoscope by slowly retracting the device.

NOTE: Endoscope should remain as straight as possible when withdrawing the device.

MR Safety Information

MR Conditional

Non-clinical testing has demonstrated that the SureClip™ Repositionable Hemostasis Clip is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3T only
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SureClip™ Repositionable Hemostasis Clip is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 25mm from the SureClip™ Repositionable Hemostasis Clip when imaged with a gradient echo or spin echo pulse sequence in a 3 Tesla MRI system.

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 3 years.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

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1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA's part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.

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Eiffestrasse 80, 20537 Hamburg Germany

EXHIBIT 2

Micro-Tech USA SureClip™ Hemostasis Clip Data Sheet

MICRO-TECH™ ENDOSCOPY

CLIP WITH CONFIDENCE
THE SURECLIP®

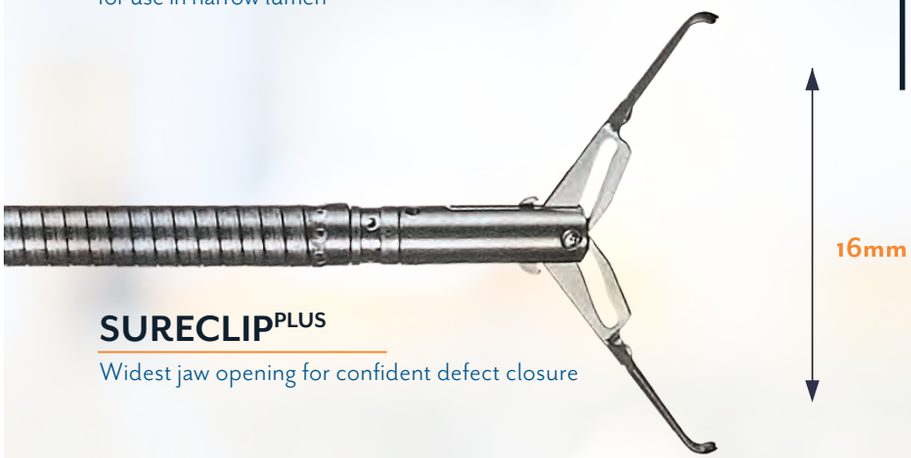
Clips need to be reliable. They need to be accurate. They need to allow you the flexibility to reposition or rotate as much as is required to deliver better outcomes.

Accurate positioning prior to deployment can reduce both procedure time and the number of clips needed to achieve hemostasis. SureClip achieves this by design delivering outstanding repositionability and reliable rotation prior to deployment, in various scope positions. SureClip's short stem aids placement in narrow lumen and improves visibility.

The proprietary clip design provides reliable deployment, may improve retention, and offers a choice of jaw sizes.

SURECLIP

Shortest stem, approximately 5mm, for use in narrow lumen



SURECLIP^PLUS

Widest jaw opening for confident defect closure

NEW PRODUCT!

SURECLIP^MINI

Lowest jaw profile for unobstructed view during placement

NEVER COMPROMISE **ON QUALITY**

DRAMATICALLY IMPROVE YOUR **BOTTOM LINE**

THROW AWAY CONTRACTS **FOREVER**

RELIABLE SUPPLY **PARTNERSHIP**

KEY BENEFITS

REPOSITIONING

SureClip's unique design permits opening and closing the jaw prior to deployment. Being able to reposition a clip may help improve placement accuracy. Fenestrations on the SureClip^{PLUS} and SureClip^{MINI} accommodate tissue and may enhance retention.

RELIABLE ROTATION

SureClip can be rotated, helping to provide the correct orientation for tissue approximation or defect closure. The rotation handle on the SureClip improves performance and enhances the user experience.

SHORT STEM

A shorter stem makes the clip less obtrusive, improving visualization of the target area, particularly when multiple clips are placed in close proximity.

SPECIFICATIONS

SURECLIP^{MINI} LOWEST PROFILE

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30415	132-5180	8	Max 2.6	235	2.8	2/Box
RC30411	132-5187	8	Max 2.6	235	2.8	10/Box

SURECLIP SHORTEST STEM

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30445	132-5724	11	Max 2.6	235	2.8	2/Box
RC30441	132-5723	11	Max 2.6	235	2.8	10/Box

SURECLIP^{PLUS} WIDEST JAW OPENING

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30385	128-5657	16	Max 2.6	235	2.8	2/Box
RC30381	128-5655	16	Max 2.6	235	2.8	10/Box

*Jaws may not open to maximum reach until placed in contact with tissue

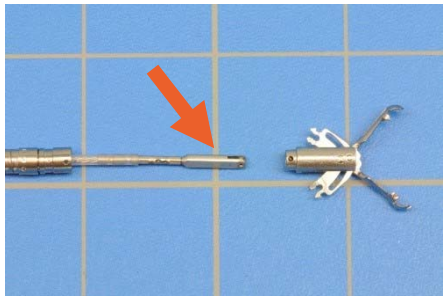
CAN'T FIND IT?

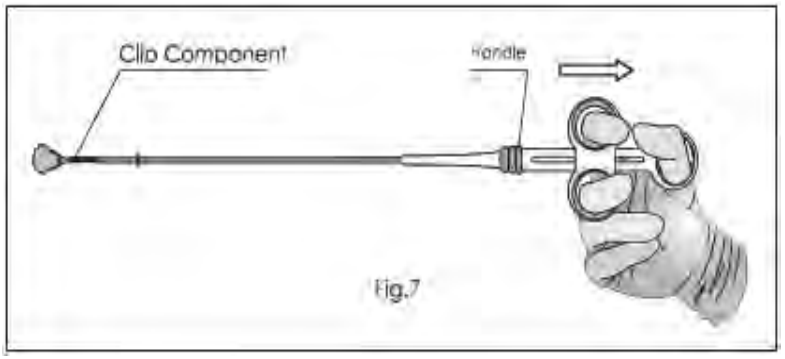
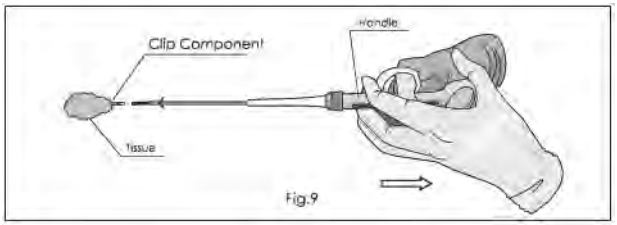
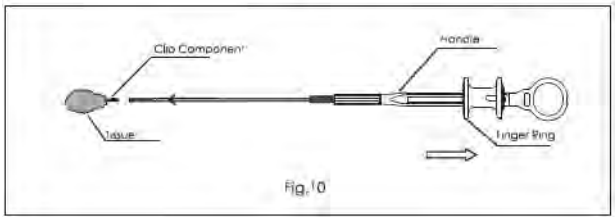
Additional items may be available. Contact us if you can't find what you need.

EXHIBIT C

Patent No. 9,980,725; Claim 1	**Micro-Tech Hemostasis Clip**
An apparatus for applying clips to tissue, comprising:	Each of the Accused Devices is a hemostasis clip for use through an endoscope to apply clips to tissue, as described more fully below. *See, e.g.*, Micro-Tech USA SureClip™ Repositionable Hemostasis Clip Instructions for Use (Exhibit 1), at 1 ("The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract"); MT00000039; MT00000093-104.
a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped;	*See* '371 infringement contentions with respect to the "a flexible sheath extending from a proximal end which, in an operative configuration, extends into a living body to a target portion of tissue to be clipped" limitation of claim 1 of the '371 patent.
a capsule comprising a proximal end and a distal end;	The Accused Devices each include a capsule that extends from a proximal end to a distal end. *See, e.g.*, Micro-Tech USA SureClip™ Hemostasis Clip Data Sheet (Exhibit 2), at 1; MT00000166. 
a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an	*See* '371 infringement contentions with respect to the "a clip assembly provided in the capsule and configured to be operably movable between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween" limitation of claim 1 of the '371 patent.

expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween; and	
a control member a distal end of which is releasably coupled to the clip assembly via a separable yoke to transmit to the clip assembly forces applied thereto to move the clip assembly between the closed and expanded configurations;	The Court has construed "control member" as a "wire or other force transmission member." *See* D.I. 140. The Court has construed "separable yoke" to be "a separable component that holds two parts in position." *See* D.I. 140. For each Accused Original/Buckle Device, the control wire, the connecting tube, the hypotube, and a pair of J-shaped (original)/C-shaped (buckle) hooks (each, a "Hook," and collectively, "Hooks") coupled to the distal end of the control wire form a control member. Each Hook hooks onto the proximal pin on opposite sides of the clip from one another to form a mechanical connection between the control wire and the clip. For each Accused Lockado Device, the control wire, the connecting tube, the yoke coupled to the distal end of the control wire, and the proximal pin fused to the yoke, form a control member. The proximal pin engages the C-shaped hooks (each, a "Hook," and collectively, "Hooks") on the proximal end of the clip arms to form a mechanical connection between the control wire and the clip. Application of a proximally directed force to the control wire draws the clip arms proximally within the capsule. When the clip arms are moved a certain distance proximally within the capsule, locking tabs located at the proximal end of each clip arm engage the internal counterbore within the capsule preventing the clip arms from traveling further proximally within the capsule. At this point, additional proximal forces applied to the control wire increases a tensile force applied to the control wire and to the connection between the Hooks and the proximal pin. When this tensile force reaches a level sufficient to uncouple the Hooks, the connection between the control wire and the clip releases, thereby uncoupling the control member from the clip assembly. The tensile force results from proximally directed force applied to the

	control wire, which is opposed by a corresponding oppositely directed force via the coil shaft, the bushing and the capsule. For the Accused Original/Buckle Devices, the Hooks (which comprise the first and second yoke arms) and connecting tube form a separable yoke that connects the control wire and the clip assembly, and holds the two components in position with respect to one another, when the Hooks hook onto the proximal pin on opposite sides of the clip. This yoke separates from the clip assembly when the Hooks separate from the proximal pin as described above. For the Accused Lockado Devices, the yoke (shown in the picture below) is coupled to the distal end of the control wire and, together with the proximal pin, connects the control wire and the clip assembly, and holds the two components in position with respect to one another, when the Hooks hook onto the proximal pin. This yoke separates from the clip assembly when the Hooks separate from the proximal pin as described above  When the clip is inserted, the clip arms are in a closed configuration. Application of a distally directed force to the control wire advances the connection between the Hooks and the proximal pin to extend the clip arms distally out of the capsule and forcing the clip arms to transition from a closed configuration to the open configuration. When the clip arms are in an open configuration, application of a proximally directed force to the control wire retracts the connection between the Hooks and the proximal pin proximally within the capsule, forcing the clip arms to transition to the closed

	configuration. *See, e.g.*, Exhibit 1, at Figs. 7, 9, and 10; MT00000093-104. The clip arms may be repeatedly opened and closed in this manner until the endoscopist is ready to deploy the clip.    Defendants assert that the Accused Original Devices "include[] nothing remotely close to a separable yoke under either Party's proposed construction." Plaintiffs disagree for the reasons just stated. Moreover, Defendants further assert, without any explanation, that "[t]he buckle and Lockado configurations of the SureClip also fail to include anything that could be the claimed 'separable yoke.'" Again, Plaintiffs disagree for the reasons just stated. Plaintiffs reserve the right to assert infringement

	based on the doctrine of equivalents to the extent Defendants provide any substantive explanation as to why the accused separable yokes described above do not satisfy this limitation in accordance with the Court's construction of the term "separable yoke."
wherein the separable yoke includes first and second yoke arms extending distally from the control member on opposite sides of the clip assembly and the clip assembly includes a connecting member extending between the first and second yoke arms coupling the yoke to the clip assembly, the first and second yoke arms being configured to be separated from the connecting member when subjected to a predetermined force by the control member to uncouple the control member from the clip assembly.	The Court has construed "connecting member" as "tension member that connects the clip arms to the yoke and biases the clip arms to an open configuration." *See* D.I. 140. As just described, for the Accused Original/Buckle Devices, the Hooks and connecting tube form a separable yoke. The Hooks extend distally from the control member on opposite sides of the clip assembly and hook onto the proximal pin on opposite sides of the clip. The proximal pin thus extends between the first and second yoke arms coupling the yoke to the clip assembly. The proximal pin is a tension member that connects the clip arms to the yoke and biases the clip arms to an open configuration. Distal movement of the control wire causes the proximal pin to move distally, and the distal movement of the proximal pin causes the clip arms to open as the clip arms are pushed out of the capsule and the slots formed in the proximal section of the clip arms ride against the distal pin. Thus, the proximal pin biases the clip arms in the open position. The yoke arms become separated from the proximal pin when subjected to a predetermined from by the control member to uncouple the control member from the clip assembly as is described in detail above. As shown in the picture above, the separable yoke of each Accused Lockado Device includes first and second yoke arms extending distally from the control member, and when coupled to the clip assembly, those clip arms are on opposite sides of the clip assembly. Each Accused Lockado Device satisfies the "connecting member" portion of this limitation under the doctrine of equivalents because any difference between the connecting member (proximal pin) of the Accused Lockado Devices and the claimed connecting member is insubstantial for purposes of the claimed invention. In particular, and among other things, the proximal pin of the Accused Lockado Devices performs substantially the same function (providing a releasable connection between the yoke arms and the clip assembly and causing the clip arms to open as they are

	pushed out of the capsule), in substantially the same way (extending between and engaging the yoke arms so as to form a connection between the yoke to the remainder of the clip assembly, in a manner such that distal movement of the connecting member in response to forces applied to the control member causes the clip arms to open as they are pushed out of the capsule, and such that application of a sufficient tensile force applied to the control wire causes the yoke to separate from the clip assembly) to achieve substantially the same result (reliable delivery and deployment of the clip) as the claimed connecting member. Defendants assert that the Accused Original/Buckle Devices "do[] not include a connecting member, which . . . is a tension member for biasing the clip arms towards an open configuration," and thus do not literally infringe this limitation. Plaintiffs disagree for the reasons stated above. To the extent it is determined, however, that the Accused Original/Buckle Devices do not literally infringe, each Accused Original/Buckle Device nevertheless satisfies this limitation under the doctrine of equivalents because any difference between the connecting member (proximal pin) of the Accused Original/Buckle Devices and the claimed connecting member is insubstantial for purposes of the claimed invention. Both the connecting member of the preferred embodiment of the '725 patent and the proximal pin of the Accused Original/Buckle Devices are solid, non-deformable structures. In particular, and among other things, the proximal pin of the Accused Original/Buckle Devices performs substantially the same function (providing a releasable connection between the yoke arms and the clip assembly and causing the clip arms to open as they are pushed out of the capsule), in substantially the same way (extending between and engaging the yoke arms so as to form a connection between the yoke to the clip assembly, in a manner such that distal movement of the connecting member in response to forces applied to the control member causes the clip arms to open as they are pushed out of the capsule, and such that application of a sufficient tensile force applied to the control wire causes the yoke to separate from the clip assembly) to achieve substantially the same result (reliable delivery and deployment of the clip) as the claimed connecting member.

Patent No. 9,980,725; Claim 2	**Micro-Tech Hemostasis Clip**
The apparatus of claim 1,	See claim 1.
further comprising a bushing coupled between the flexible sheath and the capsule,	Each of the Accused Devices comprises a bushing coupled between the flexible sheath and the capsule. An opening at the proximal end of the capsule receives the distal end of the bushing. The proximal end of the bushing is coupled to the distal end of the coil shaft. *See, e.g.*, Exhibit 2, at 1; MT00000154; MT00000166. *See also* description of bushing above and in contentions with respect to claim 1 of the '371 patent.
the bushing being releasably coupled to the proximal end of the capsule and being fixed to the distal end of the flexible sheath.	The bushing of each of the Accused Devices is fixed to a distal end of the coil shaft, and a distal end of the bushing is releasably coupled to the proximal end of the capsule. *See* description of bushing above and in contentions with respect to claim 1 of the '371 patent. Each Accused Original/Buckle Device further includes a three-pronged spring tab, with each prong of the three-pronged spring tab configured to protrude out of an opening along the circumference of the reduced diameter portion of the bushing. The proximal end of the capsule receives the reduced diameter portion of the bushing and a connection is formed when the prongs of the spring further engage holes located near the proximal end of the capsule. This connection is released when the hypotube is retracted proximally upon failure of the J-shaped hooks (Original) / C-shaped hooks (Buckle) and engages the three-pronged spring tab, causing the prongs of the spring to be pulled out of engagement with the holes located at the proximal end of the capsule, freeing the capsule and the clip from the remainder of the device so that the clip remains in the body clipped to the target tissue. *See, e.g.*, MT00000166. In this manner, the bushing is releasably coupled to the capsule via the tab (reduced diameter portion) on the distal end of the bushing engaging the opening in the proximal end of the capsule. Each Accused Lockado Device further includes two spring tabs in the proximal end of the capsule. Each spring tab is configured to protrude out of an opening along the

	circumference of the reduced diameter portion of the bushing. The proximal end of the capsule receives the reduced diameter portion of the bushing and a connection is formed when the two spring tabs in the proximal end of the capsule engage the holes at the distal end of the bushing. Upon application of a sufficient proximal force on the control wire, the spring tabs disengage from the holes in the bushing, which causes the capsule to separate from the bushing. In this manner, the bushing is releasably coupled to the capsule via the tab (reduced diameter portion) on the distal end of the bushing engaging the opening in the proximal end of the capsule.

Patent No. 9,980,725; Claim 3	**Micro-Tech Hemostasis Clip**
The apparatus of claim 2,	See claim 2.
wherein the flexible sheath is formed as a wire coil	The coil shaft of each of the Accused Devices is formed as a wire coil. *See, e.g.*, MT00000154.
and the bushing is a substantially cylindrical member extending distally therefrom with a distal portion of the bushing being received within the capsule.	The bushing of each of the Accused Devices is a substantially cylindrical member extending distally from the coil shaft, and the distal portion of the bushing is received within the proximal end of the capsule. *See, e.g.*, MT00000154; MT00000166; *see also, e.g.*, Exhibit 2, at 1. *See also* description of bushing above and in contentions with respect to claim 1 of the '371 patent.

Patent No. 9,980,725; Claim 6	**Micro-Tech Hemostasis Clip**
The apparatus of claim 1,	See claim 1.
wherein the first and second yoke arms extend distally past proximal ends of the first and second arms of the clip assembly.	In each of the Accused Devices, the distal ends of the first and second yoke arms (described above) extend distally past the proximal ends of the clip arms while the control member is coupled to the clip assembly. *See, e.g.*, MT0000020, MT0000021, MT00000157, MT00000169.

Patent No. 9,980,725; Claim 8	**Micro-Tech Hemostasis Clip**
The apparatus of claim 1,	See claim 1.
wherein a proximal end of the first arm of the clip assembly includes a projection positioned to mechanically lock with a locking feature of the capsule when the clip assembly is deployed to lock the clip assembly in the closed configuration.	In each of the Accused Devices, the proximal end of the first arm of the clip assembly includes a projection positioned to mechanically lock with a locking feature of the capsule when the clip assembly is deployed to lock the clip assembly in the closed configuration. The projection—a locking tab—engages an internal counterbore within the capsule preventing the clip from being drawn further proximally into the capsule, prevents the clip assembly from moving distally relative to the capsule, and locks the clip arms in the closed configuration over target tissue. *See, e.g.*, MT00000149, MT00000169.

Patent No. 9,980,725; Claim 9	**Micro-Tech Hemostasis Clip**
The apparatus of claim 8,	See claim 8.
wherein the projection at the proximal end of the first arm of the clip assembly is formed as a hook that mechanically interacts with the locking feature of the capsule to prevent the clip assembly from moving distally relative to the capsule.	In each of the Accused Devices, the projection at the proximal end of the first arm of the clip assembly is formed as a hook that mechanically interacts with the locking feature of the capsule to prevent the clip assembly from moving distally relative to the capsule. The projection—a locking tab—engages an internal counterbore within the capsule preventing the clip from being drawn further proximally into the capsule, prevents the clip assembly from moving distally relative to the capsule, and locks the clip arms in the closed configuration over target tissue. *See, e.g.*, MT00000149, MT00000169.

Patent No. 9,980,725; Claim 10	**Micro-Tech Hemostasis Clip**
The apparatus of claim 8,	See claim 8.
wherein a proximal end of the second arm of the clip assembly includes a projection positioned to mechanically lock with a locking feature of the capsule when the clip assembly is deployed to lock the first and second arms of the clip assembly in the closed configuration.	In each of the Accused Devices, the proximal end of the second arm of the clip assembly includes a projection positioned to mechanically lock with a locking feature of the capsule when the clip assembly is deployed to lock the clip assembly in the closed configuration. The projection—a locking tab—engages an internal counterbore within the capsule preventing the clip from being drawn further proximally into the capsule, prevents the clip assembly from moving distally relative to the capsule, and locks the clip arms in the closed configuration over target tissue. *See, e.g.*, MT00000149, MT00000169.

Patent No. 9,980,725; Claim 11	**Micro-Tech Hemostasis Clip**
The apparatus of claim 1,	See claim 1.
wherein the clip assembly is configured so that, as the clip assembly is moved distally relative to the capsule, the first and second arms of the clip assembly are moved to the expanded configuration as the first and second arms of the clip assembly project further distally from the capsule and the first and second arms of the clip assembly are drawn into the closed configuration as the clip assembly is withdrawn proximally into the capsule.	As the clip assembly is moved distally relative to the capsule, the first and second arms of the clip assembly are moved to the expanded configuration as the first and second arms of the clip assembly project further distally from the capsule. As the clip arms (made up of the clip, i.e., the multi-legged grasping device, and the clip rails) move distally through the capsule, the distal pin, which is rigidly coupled to the distal end of the capsule, rides through the slots formed in the proximal section of the clip arms to force the clip arms apart from one another into an open configuration. As the clip assembly is withdrawn proximally into the capsule, the first and second arms of the clip assembly are drawn into the closed configuration. When the clip arms are in the open configuration, application of a proximally directed force to the control wire draws the clip arms proximally within the capsule with engagement between the slots formed in the proximal section of the clip arms and the distal pin closing the clip arms over any target tissue received between the clip arms. *See, e.g.*, Exhibit 2, at 1. Such movement is reversibly operable prior to uncoupling. *See, e.g.*, *id.*, at 2 ("SureClip's unique design permits opening and closing the jaw prior to deployment."). *See also, e.g.*, MT0000020-21.

Patent No. 9,980,725; Claim 12	**Micro-Tech Hemostasis Clip**
An apparatus for applying clips to tissue, comprising:	Each of the Accused Devices is a hemostasis clip for use through an endoscope to apply clips to tissue, as described more fully below. *See, e.g.*, Exhibit 1, at 1 ("The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract").
a capsule defining a lumen therein and including openings in proximal and distal ends thereof;	The Accused Devices each include a hollow capsule that extends from a proximal end to a distal end. An opening at the proximal end of the capsule receives the distal end of the bushing coupled to the distal end of the coil shaft. During deployment, the clip arms move through the lumen of the capsule to extend distally out of an opening in the distal end of the capsule. *See, e.g.*, Exhibit 2, at 1; MT00000154; MT00000166. 
a clip assembly received within the lumen of the capsule for movement between a closed configuration in which first and second arms of the clip assembly are drawn toward one another and an expanded configuration in which the first and second arms are separated from one another to receive target tissue therebetween;	*See* contentions regarding the "clip assembly" limitation recited in claim 1 above. Those contentions are incorporated as if set forth at length herein. In each Accused Device, the clip assembly is received within the lumen of the capsule and configuration to move between a closed configuration and an expanded configuration as recited in this limitation, in the manner described in detail above.

a control member a distal end of which is releasably coupled to the clip assembly to transmit to the clip assembly forces applied to a proximal end of the control member to move the clip assembly between the closed and expanded configurations by moving the first and second arms of the clip assembly distally out of and proximally into the capsule; and	Each Accused Device includes a "control member," as is described above with respect to claim 1, and the control member of each Accused Device is releasably coupled to the clip assembly and configured to transmit to the clip assembly forces applied to a proximal end of the control member to move the clip assembly between the closed and expanded configurations by moving the first and second arms of the clip assembly distally out of and proximally into the capsule, in the manner described in detail above.
a separable yoke connecting the control member to the clip assembly, the yoke including first and second yoke arms extending distally from the control member within the capsule on opposite sides of the clip assembly, the clip assembly including a connecting member extending between the first and second yoke arms coupling the yoke to the clip assembly, the first and second yoke arms being configured to be separated from the connecting member when subjected to a predetermined force by the control member to uncouple the control member from the clip assembly.	Each Accused Device includes (either literally or under the doctrine of equivalents) a "separable yoke" that has first and second yoke arms which, when coupled to the clip assembly, extend distally from the control member within the capsule on opposite sides of the clip assembly, as is described above with respect to claim 1. Moreover, the clip assembly of each Accused Device also includes (either literally or under the doctrine of equivalents) a connecting member that extends between the first and second yoke arms coupling the yoke to the clip assembly, with the first and second yoke arms being configured to be separated from the connecting member when subjected to a predetermined force by the control member to uncouple the control member from the clip assembly, in the manner described in detail above.

EXHIBIT 1

Micro-Tech USA SureClip™ Repositionable Hemostasis Clip Instructions for Use

MICRO-TECH ENDOSCOPY

SureClip™
SureClip™ PLUS
SureClip™ MINI
Repositionable Hemostasis Clip

Instructions for Use

Micro-Tech (Nanjing) Co., Ltd.

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

The SureClip™ Repositionable Hemostasis Clip is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:
endoscopic marking,
hemostasis for
(a) mucosal / sub-mucosal defects < 3cm,
(b) bleeding ulcers,
(c) polyps < 1.5cm in diameter,
(d) diverticula in the colon,
As a supplementary method, closure of GI tract luminal perforations <20mm that can be treated conservatively

CONTRAINDICATIONS

1. Mucosal / submucosal defects greater than 3cm;
2. Polyps greater than 1.5 cm in diameter;
3. The patient with poor general condition who cannot tolerate endoscopy;
4. The patient has narrow upper digestive tract where endoscope cannot pass through;
5. The patient has serious coagulation disorders and hemorrhagic diseases;
6. The patient is allergic to the device and the drugs used in the operation;
7. The patient who is not suitable to use the product per the diagnosis;
8. The patient or the families are uncooperative.

POTENTIAL COMPLICATIONS

1. Inflammation of tissue, perforation, bleeding or mucosal damage for the patient;
2. Infection, septicemia, etc;
3. Complications which are not currently known or observed may be present.

WARNINGS

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. The product is only intended for adult populations.
4. The clips are stainless steel. Do not use them on a patient who is severely allergic to metals. This device is not made with natural rubber latex.
5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. Operation of this instrument is based on the assumption that open surgery is possible as an emergency measure if the clip cannot be detached from the instrument or if any other unexpected circumstance takes place.
7. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
8. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.
9. Do not use this instrument when hemostasis cannot be verified visually within the endoscopic field of view.
10. Do not operate the spiral tube and clip with excessive force as this may cause damage to the device.
11. It may be difficult to stop bleeding depending on the situation. Prepare more than one hemostasis device. Some devices may be used together for best result.
12. Bleeding may occur on the clipping site, depending on the local condition. Check the patient for any re-bleeding after the procedure as appropriate.
13. Always observe the endoscopic image during operation. If the clip deploys prematurely, remove it with foreign body retrieval forceps.
14. Limited studies indicate that lesions located in the esophagus and the lesser curvature of the stomach may be difficult to treat with forward-viewing endoscope.
15. Limited studies indicate that the treatment of esophageal varices may require

clipping in combination with a sclerosing agent.

16. Limited studies indicate that clipping hard or severely fibrotic lesions to achieve hemostasis may be more difficult.
17. Limited studies have shown that the number of clips required for hemostasis may vary depending upon the anatomical site, histology, lesion type and patient condition and history. A sufficient quantity of clips should be prepared in consideration of all of these factors prior to the procedure.
18. Limited studies indicate that the use of clips in the presence of bacterial contamination may potentiate or prolong infection.

【 Product Name 】SureClip™ Repositionable Hemostasis Clip
【 Packaging 】Packed in pouch
【 Production Date 】 See packaging
【 Sterilization 】 Sterilized by EO (ethylene oxide) gas
【 Shelf Life】 3 years
【 Compatible Working Channel 】≥ φ2.8mm

STRUCTURE

SureClip™ Repositionable Hemostasis Clip includes a clip component, distal end of spring tube, proximal end of spring tube and handle component (Fig.1 and Fig.2).

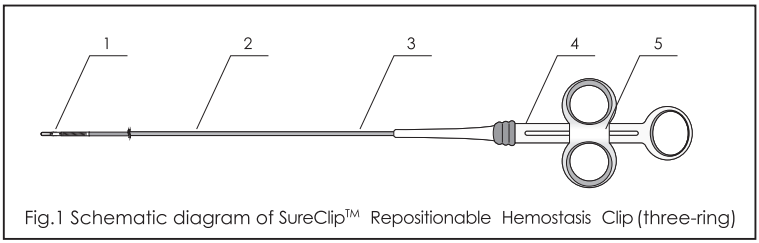


Fig.1 Schematic diagram of SureClip™ Repositionable Hemostasis Clip (three-ring)

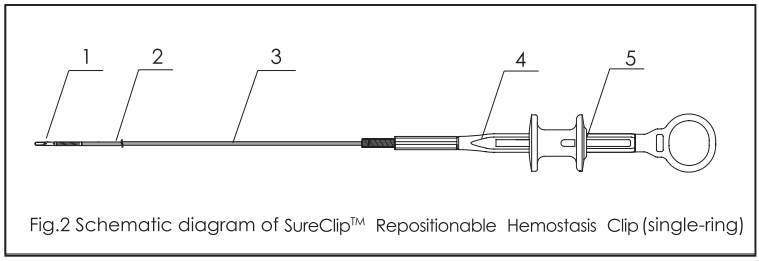


Fig.2 Schematic diagram of SureClip™ Repositionable Hemostasis Clip (single-ring)

1. Clip component 2. Distal end of spring tube 3. Proximal end of spring tube
4. Handle component 5. Finger Ring

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged.
4. Verify the expiration date. Do not use if expired.
5. Open the package carefully using acceptable aseptic technique.
6. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
7. Before use, check the clip and the spring tube to ensure that there are no sharp edges. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
8. Prior to use, remove the protective sleeve and gently open and close the device to confirm it is functioning.

NOTE: Excessive force may result in the clip deploying before use.

NOTE: Hyper-extending the finger rings away from thumb ring should be avoided. Excessive force may damage the device and affect performance.

INSTRUCTIONS FOR USE

1. The device is compatible with an endoscope channel of 2.8mm or larger.
2. Carefully insert device into endoscope channel, ensuring that the clip is in the closed position (See Fig.3 and Fig 4).

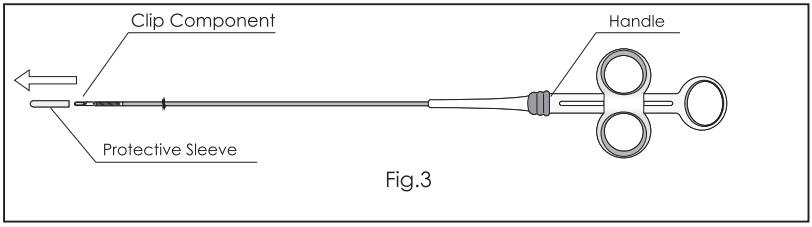


Fig.3

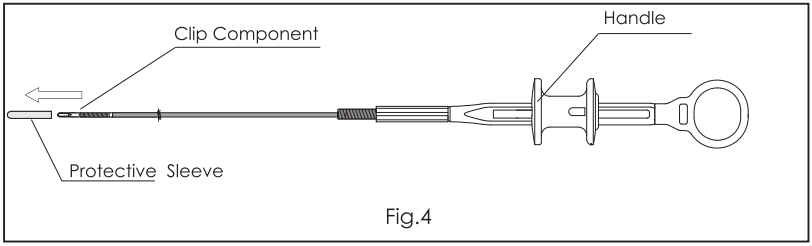


Fig.4

3. Advance the clip in small incremental movements towards the target site. Once in the instrument channel, there is no need to apply closure pressure on the handle.

NOTE: Applying excessive closure pressure to the handle during insertion, may result in detachment of the clip.

NOTE: Endoscope should remain as straight as possible when inserting the device.

NOTE: When introducing the device, in an endoscope in a tortuous position, straightening the endoscope may improve passage and exposure of the clip. With the clip in place, carefully reposition the endoscope for treatment.

4. When in endoscopic view, gently open the clip by gently sliding the finger ring forward.
5. Clip can be rotated clockwise or counter-clockwise by slowly turning the handle component until desired position is achieved. During rotation, the handle component and finger ring should be allowed to rotate. (See Fig.5 and Fig.6)

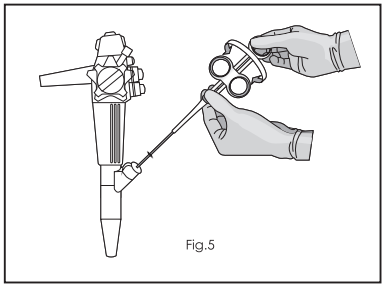


Fig.5

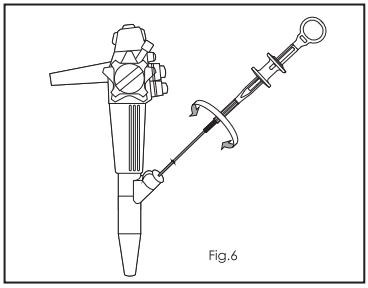


Fig.6

6. Advance the device until contact is made with the targeted site.
7. When satisfied with clip positioning, close the clip onto the tissue by pulling the finger rings back until tactile resistance is felt in the handle. The clip position may now be assessed prior to deployment. (See Fig.7 and Fig.8)

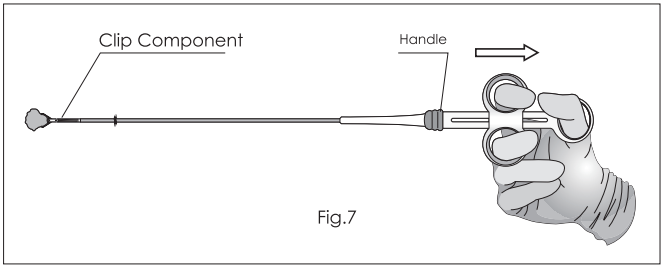


Fig.7

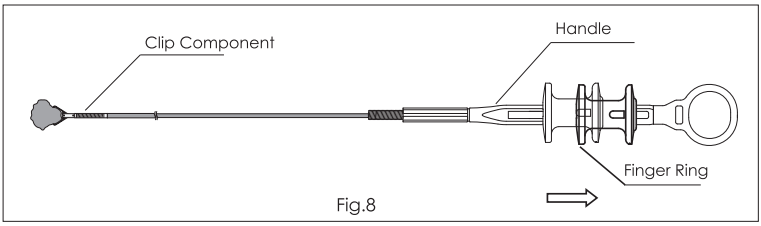


Fig.8

If the clip is not in its desired position, the clip may be re-opened and repositioned.

NOTE: Do not continue to pulling back the finger rings beyond the tactile resistance until you are ready to deploy the clip, otherwise you may not be able to re-open the clip. If you hear or feel a click, the clip cannot be re-opened.

8. To deploy the clip, continue pulling back the finger rings beyond the tactile resistance point .You will hear an audible snap when the clip component detaches. (See Fig.9 and Fig.10).

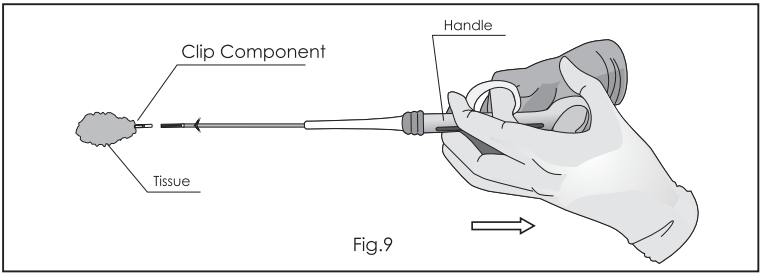


Fig.9

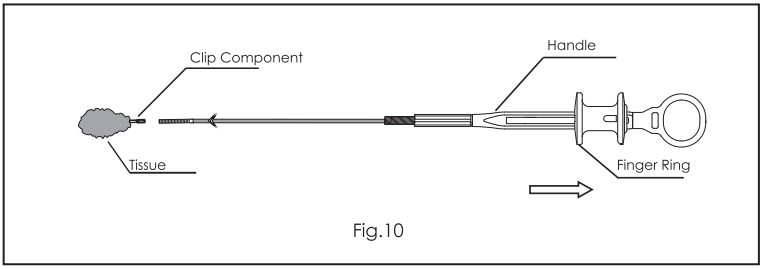


Fig.10

NOTE: If the clip did not immediately detach from the catheter, then apply gently movement of the catheter or endoscope to unseat the clip.

NOTE: Do not advance the finger rings after deployment as this may damage the device.

9. Remove sheath from endoscope by slowly retracting the device.

NOTE: Endoscope should remain as straight as possible when withdrawing the device.

MR Safety Information

MR Conditional

Non-clinical testing has demonstrated that the SureClip™ Repositionable Hemostasis Clip is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5T and 3T only
- Maximum spatial field gradient of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SureClip™ Repositionable Hemostasis Clip is expected to produce a maximum temperature rise of less than 2°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 25mm from the SureClip™ Repositionable Hemostasis Clip when imaged with a gradient echo or spin echo pulse sequence in a 3 Tesla MRI system.

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 3 years.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

Limited Warranty and Disclaimers:

1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA's part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products' integrity, reliability, or performance.

2. Disclaimer and Release. **THE WARRANTIES, OBLIGATIONS, AND LIABILITIES OF Micro-Tech USA AS SET FORTH HEREIN ARE EXCLUSIVE. BUYER HEREBY WAIVES ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, WITH RESPECT TO THE PRODUCTS AND ANY OTHER GOODS OR SERVICES DELIVERED BY BUYER, INCLUDING, BUT NOT LIMITED TO: (1) ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND (2) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.**

3. Implied Warranties. The purchase of products may be subject to laws in the territories applicable to the sale of the products by Micro-Tech USA to Buyer that impose implied warranties, conditions, or obligations that cannot be excluded, restricted, or modified, or can only be excluded, restricted, or modified to a limited extent. The provisions of Paragraphs 2 and 4 shall apply to the greatest extent allowed by such laws.

4. Limitation of Liability. **EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, Micro-Tech USA'S LIABILITY UNDER THIS WARRANTY IS LIMITED TO: (a) THE REPLACEMENT OF THE PRODUCTS OR THE RE-SUPPLY OF EQUIVALENT PRODUCTS; (b) THE REPAIR OF THE PRODUCTS OR PAYMENT OF THE COST OF REPAIRING THE PRODUCTS; or (c) PAYMENT OF THE COST OF REPLACING THE PRODUCTS OR ACQUIRING EQUIVALENT PRODUCTS. MICRO-TECH USA SHALL HAVE NO OBLIGATION OR LIABILITY, WHETHER ARISING IN CONTRACT (INCLUDING WARRANTY), TORT (INCLUDING ACTIVE, PASSIVE, OR IMPUTED NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY) OR OTHERWISE, FOR ANY SPECIAL, CONSEQUENTIAL, PUNITIVE,**

INCIDENTAL, OR INDIRECT DAMAGES, OR FOR LOSS OF USE, LOSS OF REVENUE, LOSS OF BUSINESS, LOST PROFIT, OR OTHER FINANCIAL LOSS ARISING OUT OF OR IN CONNECTION WITH ANY PRODUCT OR OTHER GOODS OR SERVICES FURNISHED BY MICRO-TECH USA, EVEN IF MICRO-TECH USA WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.

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EXHIBIT 2

Micro-Tech USA SureClip™ Hemostasis Clip Data Sheet

MICRO-TECH™ ENDOSCOPY

CLIP WITH CONFIDENCE
THE SURECLIP®

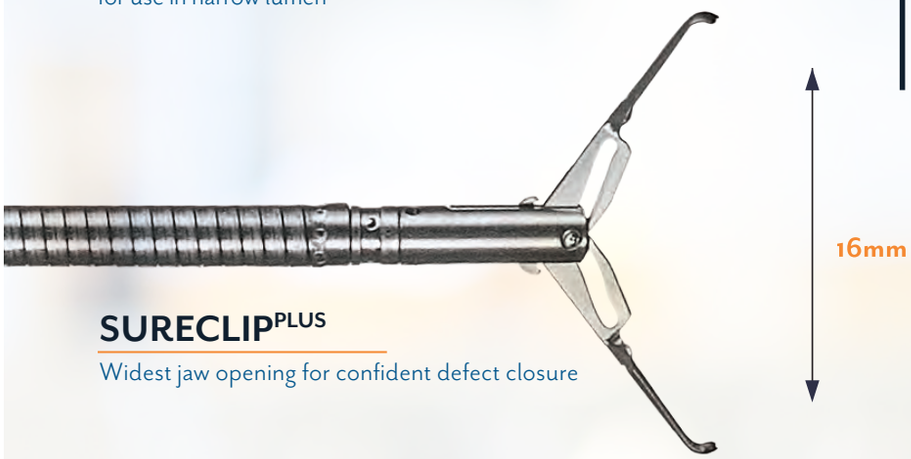
Clips need to be reliable. They need to be accurate. They need to allow you the flexibility to reposition or rotate as much as is required to deliver better outcomes.

Accurate positioning prior to deployment can reduce both procedure time and the number of clips needed to achieve hemostasis. SureClip achieves this by design delivering outstanding repositionability and reliable rotation prior to deployment, in various scope positions. SureClip's short stem aids placement in narrow lumen and improves visibility.

The proprietary clip design provides reliable deployment, may improve retention, and offers a choice of jaw sizes.

SURECLIP

Shortest stem, approximately 5mm, for use in narrow lumen



SURECLIP^PLUS

Widest jaw opening for confident defect closure

NEW PRODUCT!

SURECLIP^MINI

Lowest jaw profile for unobstructed view during placement

NEVER COMPROMISE **ON QUALITY**

DRAMATICALLY IMPROVE YOUR **BOTTOM LINE**

THROW AWAY CONTRACTS **FOREVER**

RELIABLE SUPPLY **PARTNERSHIP**

KEY BENEFITS

REPOSITIONING
SureClip's unique design permits opening and closing the jaw prior to deployment. Being able to reposition a clip may help improve placement accuracy. Fenestrations on the SureClip^{PLUS} and SureClip^{MINI} accommodate tissue and may enhance retention.

RELIABLE ROTATION
SureClip can be rotated, helping to provide the correct orientation for tissue approximation or defect closure. The rotation handle on the SureClip improves performance and enhances the user experience.

SHORT STEM
A shorter stem makes the clip less obtrusive, improving visualization of the target area, particularly when multiple clips are placed in close proximity.

SPECIFICATIONS

SURECLIP^{MINI} LOWEST PROFILE

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30415	132-5180	8	Max 2.6	235	2.8	2/Box
RC30411	132-5187	8	Max 2.6	235	2.8	10/Box

SURECLIP SHORTEST STEM

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30445	132-5724	11	Max 2.6	235	2.8	2/Box
RC30441	132-5723	11	Max 2.6	235	2.8	10/Box

SURECLIP^{PLUS} WIDEST JAW OPENING

Order Number	Henry Schein Item Number	Opening Width (mm)	Sheath Diameter (mm)	Working Length (cm)	Minimum Channel Size(mm)	Package Units
RC30385	128-5657	16	Max 2.6	235	2.8	2/Box
RC30381	128-5655	16	Max 2.6	235	2.8	10/Box

*Jaws may not open to maximum reach until placed in contact with tissue

CAN'T FIND IT?
Additional items may be available. Contact us if you can't find what you need.

CERTIFICATE OF SERVICE

I, Nicholas D. Picollelli, Jr., Esquire, hereby certify that on July 31, 2020, I caused a true and correct copy of the foregoing document to be served upon the following counsel of record by electronic mail:

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YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Nicholas D. Picollelli, Jr.

July 31, 2020

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Attorneys for Plaintiffs, Boston Scientific Corporation and Boston Scientific Scimed, Inc..

TAB 2

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.,	:	CIVIL ACTION
Plaintiffs,	:	
vs.	:	
MICRO-TECH ENDOSCOPY USA INC., MICRO-TECH (NANJING) CO., LTD., and HENRY SCHEIN INC.,	:	
Defendants.	:	NO. 18-1869-CFC-CJB

- - -

Wilmington, Delaware
Wednesday, June 24, 2020
9:00 o'clock, a.m.
***Telephone conference

- - -

BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

- - -

APPEARANCES:

YOUNG CONAWAY STARGATT & TAYLOR, LLP
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KAREN L. PASCALE, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

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DECHERT LLP
BY: ROBERT D. RHOAD, ESQ.
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Counsel for Plaintiffs

ASHBY & GEDDES
BY: ANDREW C. MAYO, ESQ.

-and-

ORRICK, HERRINGTON & SUTCLIFFE, LLP
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CHRISTOPHER J. HIGGINS, ESQ. and
OLAMIDE OLUESI, ESQ.
(Washington, D.C.)

Counsel for Defendants

- - -

P R O C E E D I N G S

(The telephone conference was held beginning at 9:00 a.m.)

THE COURT: All right. Can we hear, let's say, plaintiffs, could you introduce yourselves, please?

MS. KRAMAN: Good morning, Your Honor. This is Pilar Kraman from Young Conaway for the plaintiffs.

With me from Young Conaway is Karen Pascale, and from Dechert is Kevin Flannery, Bob Rhoad, Joe Gribbin and Dan Roberts, and then from Boston Scientific is Eileen Hunter, Denise Lane and Todd Massal.

THE COURT: Okay. Thank you very much. And then for the defense?

MR. MAYO: Good morning, Your Honor. This is Andrew Mayo from Ashby & Geddes on behalf of the defendants, and I am joined this morning by my co-counsel from Orrick, Herrington & Sutcliff.

On the line you have Steven Routh, Vann Pearce, Christopher Higgins, and Olamide Oluesi, and we are joined by Micro-Tech USA's outside general counsel, Barbara Kramer.

THE COURT: Okay. Great. Thank you.

All right. So I think the first issue is the preamble, whether it's limiting. Correct?

MR. FLANNERY: Your Honor, this is Kevin Flannery for plaintiffs.

THE COURT: All right. I don't think I need argument on that. I read the briefing. And let me check one thing. Yes, I don't think I need briefing on this. I think the preamble is limiting.

Whether to treat a preamble as a limitation is a determination resolved routinely on a review of the entire patent to gain an understanding of what the inventors actually invented and intended to encompass by that claim, or by the claim. When reciting additional structure or steps that are underscored as important by the specification, the preamble may operate as a claim limitation, and, for instance, in Poly-Am L.P. against GSE Lining Technology, Inc., 383 F3d., 1303, the Federal Circuit found that the preamble phrase "blown film" was limiting because a review of the entire patent showed that the inventor considered that the blown film preamble language represented an important characteristic of the claimed invention. The specification there was replete with references to the invention as a blown film liner, including the title of the patent itself and the summary of the invention.

The phrase blown film was used repeatedly to describe the preferred embodiments, and the entire preamble

blown film textured refiner was restated in each of the patent's seven claims.

Similarly, in Deere & Company against Bush Hog at 703 F3d., 1349, the Federal Circuit found that the preamble phrase "rotary cutter deck" was limiting because that phrase provided structure that the specification underscored as important.

As the Court noted in Deere, the specification repeatedly referred to the present invention as an improved deck for a rotary cutter or a rotary cutter deck. The title of the patent, the summary of the invention and every drawing described the invention as a deck for a rotary cutter and the specification explained that the invention addressed concerns specific to rotary cutters.

Here as in Deere, the specification underscores the importance of the preamble phrase "for use through an endoscope," and the phrase provides structure to a limitation of the claim.

The title of the '245 patent is device and method for through scope endoscopic, hemostatic clipping. The abstract describes the invention as including a "through the endoscope, hemostatic clipping device," and the field of the invention states that the present invention relates to compression clips delivered to a target site through an endoscope. And I point you there to column 1, lines 7

through 10.

Moreover, the background asserts that the invention seeks to solve a problem that the endoscopist faces, and that's at column 1, line 20.

The written description establishes that the term through an endoscope provides structure for the axially rigid sheath limitation in the claims. Specifically, the written description establishes that the term requires that the axially rigid sheath must be designed to fit through an endoscope.

The written description states that the sheath has, "an outside diameter of slightly less than the inside diameter of the working channel of the endoscope." That's at column 6, lines 32 through 33. It further states that, "It is flexible enough to be manipulated through a flexible endoscope." That's at column 6, lines 35 through 36. And, further, that it may have a protective coating "to increase the lubricity between the endoscope working channel and the device," and that is at column 15, lines 3 through 5.

Defendants argue that the preamble is not limiting because it merely states an intended use of the claim's device, but as explained above, the for use through an endoscope phrase recites more than just an intended use for the device. It recites a structure that the written

description underscores as important -- indeed, critical to the invention.

The defendants also argue that the preamble is not limiting because the body of the claims define a structurally completed invention, but when viewed in the context of the written description, the body of claim 1 does not represent the complete invention disclosed in the written invention because it fails to include the necessary limitation of through an endoscope.

Without the endoscope limitation, the claims would leave out structure that the written description establishes is necessary and important for the invention just as the claim in Deere would have failed to cover the fundamental characteristic of the claimed invention without the preamble's rotary cutter deck limitation and would instead cover only deck wall generally.

All right. Let's turn to the next claim, which I believe is the control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip. I will hear first from plaintiffs.

MR. FLANNERY: Okay. Thank you, Your Honor. This is Kevin Flannery for plaintiffs.

What's important here is the context, the contextual meaning of the claim term, and that comes from

the specification.

Phillips is very clear that it teaches us that the ordinary meaning of a claim term is its meaning to an ordinary artisan after reading the patent, and Boston Scientific submits that its construction, particularly with respect to the inclusion of the term, repeatedly the ability of the endoscopist to repeatedly open and close the clip is very important to the invention. As a matter of fact, it's described as a key advantage. It was the purpose of the invention in order to distinguish over the prior art.

As your Honor just referenced, this is important to the endoscopist to perform the procedure. The prior art, as it's clear from the specification, that in the prior art, the endoscopist would also have to use -- would fire the clip too early.

The specification -- I will anchor us at slide 9 here. The problem with the prior art device is once the endoscopist was committed to firing, that was it. The jaw closer was not reversible and this resulted in huge waste of time and dollars spent in the operating room. The endoscopist would -- these are procedures where the endoscopist often uses multiple clips, sometimes as many as five, perhaps even ten, to try to close up the procedure, and if they miss, that's a wasted clip, and so they have to

fire again. And this would go on.

So what was the key with Boston Scientific's invention here was giving the opportunity to reverse the open and close process as many times as necessary for the endoscopist to be able to feel that he was at the spot that he or she wants to deploy the clip. Very important.

The specification at column 245 -- I'm sorry, column 2, lines 25 to 31 as we show on slide 9 practically describes what it means by definition to be reversible. If the endoscopist is committing -- is committed to firing and can't reverse that, then it's done, and it could result in a waste.

And so the specification is replete with instances describing these key advantages and how the key advantages of being reversibly operable and opening and closing, and it has to be the ability to repeat that. It's the, for example, if you were to consider, well, could it just be what is one operation of opening and closing, that wouldn't make sense in the context of the specification because the clip is in an open position and if the endoscopist started to close it and doesn't like his spot, well, there's one series of opening and closing.

So if the endoscopist doesn't like the spot, he or she would have to reopen the clip, and by definition, they would have to then say if they liked the spot, close.

So there are two instances of opening and closing, and that process repeats throughout the procedure until the endoscopist is ready to fire, and that's very important. That was necessary to distinguish over the prior art. Defendants' construction pays no merit to any of that. It's practically purposefully vague to allow a single inline push or single inline pull, and Boston Scientific's construction is within the context based upon, rooted in the context of the specification, the plain and ordinary meaning in the specification as taught by Phillips, and that requires that the endoscopist have the ability to reverse the operation. Again, this is reversibly operable, so to be able to reverse the operability, the endoscopist has to have the opportunity to repeatedly open and close the clip.

And I'm mindful of the Court's order from yesterday about the amount of time spent, so I will stop there.

THE COURT: All right. Let me just ask you one question.

MR. FLANNERY: Sure.

THE COURT: You can look at Figure 12, figures 12 and 14 in the patent?

MR. FLANNERY: Yes, your Honor.

THE COURT: And as I understand it, defendants are saying that these figures show that the control wires,

they can move in both the proximal and distal direction, but it is only the proximal pulling that opens and closes the clip-ons.

Do you agree with that?

MR. FLANNERY: Well, I don't think that that is inconsistent.

THE COURT: That's not my question. My question is: Do you agree with it?

MR. FLANNERY: I agree that there's a pulling that ultimately ends up in the separation of the clip from the rest of the device. That's the way it is in all of the other embodiments, but THE endoscopist still has the opportunity in these embodiments to push and pull, to open and close. As a matter of fact, Figure 14 is described as being like a clothespin, and what better way to envision the repeated opening and closing of something to carry out the procedure.

But then ultimately, when the -- so there's a, kind of like a part of a push and a part of a pull and part of a push and part of a pull, and that's how you get this reversibility, this repeating. Then, ultimately, when the endoscopist is in position and wants to fire, then there has to be a one-way pulling or something like that.

So the answer to Your Honor's question is, yes, that's ultimately how the clip is fired, and I think that

that is consistent with our position.

THE COURT: All right. So you're saying only the proximal pulling opens and closes the clip on. You agree with that?

MR. FLANNERY: No, your Honor. I think the product --

THE COURT: Okay. I've got you taking both positions, so maybe I don't understand.

MR. FLANNERY: I think you meant the --

THE COURT: As I understand the defendants' position, it is only the proximal pulling opens and closes the clip, clip-ons. And --

MR. FLANNERY: I disagree with that.

THE COURT: I'm sorry. As depicted in 12 and 14. And you disagree with that because you say, no, it's both pulling and pushing that opens and closes?

MR. FLANNERY: Yes. And then what I was answering, your Honor, and I apologize for any confusion, is the ultimate pulling that fire the clip is the final closing. That's --

THE COURT: Right. Okay. All right. Okay. Let me hear from the defendants.

MR. HIGGINS: Good morning, Your Honor. This is Chris Higgins for the defendants.

So --

THE COURT: Mr. Higgins, let me ask you at the outset then. So just so I understand your position, are you saying that it's only the proximal pulling that opens and closes, or is the pulling -- is the opening and closing accomplished by pushing and pulling?

MR. HIGGINS: Are you referring to the Figure 12 that you were discussing with opposing counsel, Your Honor, or just in general in your construction?

THE COURT: First of all, in general, and then, secondly, with respect to Figure 12 and 14.

MR. HIGGINS: So first in general, our position is that the claim as written, the language encompasses either. You can have a pushing or pulling that opens and closes the clip legs, or as in Figure 12, you can just have a proximal pulling, or as in Figure 19, you can have just a distal pushing of the control wire that both opens and closes the clip legs. The claim language does not specify a particular direction of movement or that both are required to perform the opening and closing operation.

THE COURT: Okay. So then would you have a problem with describing the movement as being pushed and pulled?

MR. HIGGINS: No. Push and pull would be consistent with the proximal and distal movement that we have in our construction, so that would be, that would be

fine with us.

THE COURT: Okay. So would you have a problem with me construing it then as when the control wire is coupled with the clip, the control wire can be both pushed and pulled to open and close the clip legs?

MR. HIGGINS: Yes. That would be, that would be fine with us, Your Honor, if it's consistent with our understanding of the claim language as encompassing all of those operations that I described.

THE COURT: Well, I don't know what that caveat is. I mean, my point is, I just wonder whether we can't just have an agreement here. I'm not going to -- you know, I don't see repeatedly as being part of the construction, and so my inclination is to construe this term as "when the control wire is coupled to the clip, the control wire can be both pushed and pulled to open and close the clip leg." And we might have agreement there, it seems. I'm wondering if we do.

So do you agree? Are you okay with that construction?

MR. HIGGINS: Yes, we're fine with that, Your Honor.

THE COURT: All right. So what about Boston Scientific?

MR. FLANNERY: Well, Your Honor, I think the

better construction is that the wire, instead of can, that the wire must be both pushed and pulled to open and close the clip legs. There has to be reversibility. I'm concerned that the defendants -- the defendants have made it clear in the IPR --

THE COURT: Well, can I just interrupt you? Wait, wait, wait.

MR. FLANNERY: Yes.

THE COURT: I mean, your proposed construction says can be. Why are you adding must? Where did that come in?

MR. FLANNERY: Well, because to capture the repeatedly concept. I mean, I don't know how you can -- I'm concerned that there would be a reading of that, just a one-way pulling can be both pushed or pulled. The possibility of that exists in the prior art. The product wouldn't work, but it still exists. It has the capability to be both pushed and pulled to open and close the clip legs.

THE COURT: Right. Can be.

MR. FLANNERY: When you take out repeatedly -- with all due respect, Your Honor, when you take out repeatedly, it leaves it, in our view, still vague to encompass a one-way, one direction of pulling that results in an opening and then a closing of the clip legs, and

that's the problem here, because that's not the invention. That's the prior art.

So I'm concerned that even Your Honor's construction does not distinguish -- does not necessarily distinguish over the prior art. I'm sure defense counsel will find some way to still cite that same prior art that was distinguished during the IPR or during prosecution.

THE COURT: All right. Well, I'm going to construe the term as "when the control wire is coupled to the clip, the control wire can be both pushed and pulled to open and close the clip legs."

A Court should construe claim terms according to the plain and ordinary meaning that the term would have to a POSITA when read in the context of the specification, or I should say the written description and prosecution history. Actually, in that case, I do mean both specification to include the written description claimed.

There are only two exceptions to this general rule. First, when a patentee sets out a definition and acts as its own lexicographer, or, two, when the patentee disavows the full scope of the claim term either in the specification or during prosecution. In either event, lexicography or disavowal must be clear and unmistakable. Here, because the specification does not define or disavow the scope of the term "the control wire reversibly operable

both to open the at least two clip legs and to close the at least two clip legs when the control wire is coupled to the clip." I will construe the term according to its plain and ordinary meaning, and that meaning is "when the control wire is coupled to the clip, the control wire can be both pushed and pulled to open and close the clip legs."

Defendants seek to divide the term into two parts so that the wire is able to move in two directions and separately the wire's movement in either direction can both open and/or close the clip legs. Thus, the wire's movement in one direction could open and close the clip legs. But the claim language does not support that construction, and the defendants have not pointed to anything in the intrinsic record that clearly limits the term of such embodiment.

Claim 1 requires that the control wire be reversibly operable both to open and to close the legs. That language established that the control wire must be reversibly operable so as to both open and close the legs, not that the wire should be reversible and separately able to open and close the legs as defendants contend.

I agree with the PTAB's statement that the defendants have failed to explain how a control wire that uses a single linear movement to both open and close the clip legs is somehow reversibly operable to both open and close the clip legs.

Defendants also argue that Boston Scientific's plain meaning construction improperly inserts the word repeatedly in the claims, and I agree. Boston Scientific argues that the ability to use the wire to repeatedly open and close the legs is part of the ordinary meaning of the term reversibly operable, because reversible means that once you start an operation, closing or opening, you can reverse it and start again. Put on its face, the term reversible is not synonymous with repeatable, and although the written description mentions repeatability, the specification does not clearly and unambiguously add such a limitation to the term.

Finally, defendants argue that Boston Scientific's construction reads out the phrase when the control wire is coupled to the clip, and I agree with that and I'm going to add that to my construction of the term.

Okay. Next term. We've got clip. Let me hear from plaintiffs.

MR. FLANNERY: Yes. Thank you, Your Honor. Again, it's Kevin Flannery for Boston Scientific, and I'm just saying that for the purposes of the record because my colleague, Bob Rhoad, will argue on other terms.

So the defendants' construction here is not consistent with the intrinsic evidence. As a matter of fact, it's inconsistent with the intrinsic evidence. And

particularly, I think that the formable part of the construction I'm not going to spend much time on. It only appears once in the specification. They hardly provide any briefing on it. Really, the issue comes down in our view through this requirement of a parallel horizontal configuration as a result of the restriction requirement, restriction practice. And I respectfully submit that defendants have completely misapplied routine restriction practice, which is what happens here. Restriction practice focuses on a single element of a claim, and that is for the purpose of allowing the Examiner to do searching with respect to that particular element if the Examiner chooses to do so.

So the Examiner was looking at this claim term two legs and found that there were these different configurations and he made a restriction requirement as they often do, and the Examiner said it appeared to him, it appeared to him that none of the claims were generic with respect to that particular feature for that particular element, and Boston Scientific, the applicant, as routinely happens, disagreed with the Examiner and stated that there were generic claims with respect to that particular feature, the clip legs, the configuration.

So Boston Scientific said, here's the generic -- here's the claims that are generic with respect to that

feature. And the Examiner never pushed back on that. The Examiner never even did any searching, did absolutely nothing with respect to that feature, the configuration.

The Examiner focused, as they often do, focused on other aspects of the invention, and ultimately, the claimed invention was allowed over an entirely different element. Had the Examiner been focused on the configuration, there could have been instances where the Examiner might have found some other configuration in the prior art, one of those species that was in the claimed genus, and the construction -- I mean, the prosecution might have taken a different track there and the Examiner might have required the applicant to limit that particular element to that particular species, the parallel horizontal, if the applicant chose to, but that didn't happen here, and that hardly ever happens. That would have resulted in express limitation of the claims.

Here, this was just routine restriction practice. The applicant identified generic claims.

Those claims were allowed. They were allowed, and --

THE COURT: All right.

MR. FLANNERY: I just want to say they cite no law that the generic claim has to be generic through all features. They cite absolutely no law for that, Your Honor,

because there is none.

THE COURT: All right. Let me hear from the defendants. All right. Thank you. Let me hear from the defense.

MR. PEARCE: Thank you, Your Honor. This is Van Pearce on behalf of the defendants.

I would like to begin by addressing the deformable issue, and I'd like to start by first pointing out that the specification, this is at column 2, 5:17 through 23, discusses that there are a number different number of different types of devices that are used to apply constrictive forces to stop bleeding. Those devices are listed. The options are clamps, clips, staples, sutures, and the like.

The patent here then goes on to describe and claim clips. It's not describing or claiming these other types of devices.

The patent then goes on to claim what a clip is. The clip is a deformable, multi-legged grasping device. That's at column 5, lines 37 through 38, and that is our construction.

The problem with the plaintiffs' construction here --

THE COURT: Now, wait. Isn't that specific to a particular embodiment?

MR. PEARCE: It is describing an embodiment, but that is also the same as what the clips are for the rest of the embodiments. In other words, the clips are a deformable, multi-legged grasping device in every embodiment of the patent, and that is distinct from other devices that the plaintiffs could have claimed but chose not to that would be multi-leg devices or would be grasping device like a clamp or staple, for example, but instead they chose in the context of this invention to claim clips.

So that's our position on the deformable aspects of the claims and why we think that needs to be part of the construction.

And I will note that the plaintiffs most recently have said that they would accept the definition that we have listed here, just without the word deformable. We would submit that the entire definition should control here.

Then if I can address the issue --

THE COURT: Well, wait. Hold on. So I'm having a hard time on the clear lexicography. Put that aside. I mean, I'm inclined to construe this as a multi-legged grasping device. Are you good with that?

MR. PEARCE: No. We would not be okay with that just because we think that would encompass other types of devices that are not clips. We think it would include, for

example, potentially a clamp or a staple, which would be a multi-legged device, and potentially a grasping device, but is not a clip.

THE COURT: All right. But you have not -- and the only clear lexicography you're pointing to is column 5 at line 37. Is that right?

MR. PEARCE: Yes, we're pointing to that, and I think it should be read in context with the other parts of the specification, particularly the discussion earlier in the specification, where it describes that there are other types of devices that could be used to close wounds that are not clips.

THE COURT: Okay. All right. I'm going to adopt the portion of the defendants' construction that Boston Scientific has agreed to, and that is the multi-legged grasping device. That's how I'm going to construe this term. The defendants seek to further limit that term to a deformable device, that's number one. And then, number two, in the parallel horizontal configuration.

So defendants argue that the inventors acted as lexicographers when they defined the term clip as a deformable, multi-legged grasping device, but the definition from the written description that they cite only applies to a single embodiment of the claimed clip. The full quote

that defendants cite states, and I quote, "The clip, 101, is a deformable, multi-legged grasping device attached to the distal portion of a flexible shaft, the sheath 111, via a frangible link, the J-hook 107."

The definition defendants cite thus defines clip 101, embodiment shown in Figure 1 of the specification, and defendants do not even seek to construe clip as requiring the latter half of the definition from which they quote. If the passage were clear lexicography as the defendants contend, then the entire definition should apply to the term.

Second, defendants argue that the inventors clearly limited the clip to a parallel horizontal configuration during prosecution, but the prosecution history only limits the scope of a claim if it shows that the patentee clearly disavowed the claim scope during prosecution. And the passage from the prosecution that defendants cite does not amount to a clear disavowal. The passage establishes that during prosecution, the Examiner stated that the applicant is required to elect a single disclosed species to which the claims shall be restricted if no generic claim is finally held to be allowable.

Boston Scientific elected the parallel horizontal species, as Boston Scientific also identified generic claims, and most of those generic claims were

allowed. It is thus not clear that Boston Scientific limited the claim to the parallel horizontal configuration, and it would be inappropriate to limit a broad definition of a claim based on prosecution history that is itself ambiguous.

All right. Let's turn to the next term. This is the breakable link adapted to be broken, and it's in claims 1 and 15 of the '245 patent.

And let me see. Just give me a second here. Let me hear from plaintiffs.

MR. FLANNERY: Yes. Thank you, Your Honor. This is Kevin Flannery.

Boston Scientific's construction here makes everything consistent in the intrinsic record. It does not read out, it would not read out the first embodiment described as defendants' construction would do.

THE COURT: You broke off. Do you want to repeat?

MR. FLANNERY: I'm sorry, Your Honor. Yes.

So I said that Boston Scientific's construction makes everything consistent with respect to the intrinsic record. It does not read out the first embodiment describing a J-hook.

There's discussion in the briefing regarding claim 3 and claim 12. Boston Scientific's construction

would be what makes both of those fully consistent whereas defendants' does not.

And I think what's important here is we have to focus on the intrinsic record and not -- defendants want the foreign prosecution to control, but that shouldn't be the case.

And the intrinsic --

THE COURT: Well, sorry to interrupt. You know, this is hard on the phone, I realize, but you said makes everything consistent. I mean, how is that so when you look at claim 12 and claim 1 together?

MR. FLANNERY: Well, claim 12 recites that there's a frangible link and a breakable link. There can be two links in a device, Your Honor, so there can be, and, in fact, one -- you could have two J-hooks, you know, going down the line along the device. You could have --

THE COURT: Yes, but the language is, it says, wherein the frangible link is at least one of wire reversibly deformed into a J-hook, and the breakable link, wherein the J-hook is able to be straightened by the first predetermined tensile force and wherein the breakable link is able to be broken by the first predetermined tensile form. So it's differentiating between the breakable link and the J-hook. Right?

MR. FLANNERY: Claim 12 arguably does that, Your Honor, but that's inconsistent with claim 3, where claim 3, which is dependent on claim 1 only, claim 1 recites -- and we have to look at this as a person of ordinary skill in the art would read this. Claim 1 recites that there's a breakable link and broken. When the breakable link is broken, there's the uncoupling of the clip.

Claim 3 recites solely the J-hook, and it says, when the J-hook is straightened, the control wire uncouples from the clip. The inescapable conclusion of reading that is that the J-hook is the breakable link in claim 3. And we've argued this in the briefing.

So to the extent that claim 12 is inconsistent with that, I respectfully submit that Your Honor can't just choose between claim 12 trumps claim 3. They both have to be considered in the analysis. It's inescapable that claim 3, that the breakable link in claim 3 is the J-hook.

THE COURT: All right. Let me hear from the defense on that.

MR. HIGGINS: Your Honor, this is Chris Higgins again for defendants.

I will start with claim 3 and 12 that were just addressed, and it's important to keep in context how these claims came to be where claim 1, when it was originally

filed, did not include the limitation of a breakable link. Rather, the breakable link was in dependent claim 4 at the time, relied on claim 1.

Separately, dependent claim 3, which has the J-hook, independently relied on claim 1. During prosecution, the applicants amended claim 1 and rolled into that the breakable link that was in claim 4. They then canceled claim 4.

Claim 3 was left dependent on claim 1 as a mistake, and, in fact, the Examiner during prosecution pointed out to Boston Scientific that this is inconsistent and there's -- in fact, nothing is claimed in claim 3 in addition to claim 1, because it is a mistake.

And, again, as Your Honor pointed out, claim 12 does differentiate between a frangible link that's a J-hook and which is deformed or straightened as opposed to a breakable link, which indeed breaks.

And the position that claim 12 takes and differentiates these two terms is the exact position that Boston Scientific has taken for this exact same claim phrase in the exact same specification in Europe.

THE COURT: So let me ask you about that. I mean, that's extrinsic evidence. Right?

MR. FLANNERY: It is extrinsic evidence, but the Federal Circuit has said that in circumstances where the

claim language and the specification are the same, you can look at these statements if they are clear. And we would submit that as we cite in our brief and on slide 25, there isn't just one time where Boston Scientific made this statement. They made this statement over and over and over again, both in prosecution to distinguish prior art, and in opposition proceedings against Micro-Tech's in Europe, where they have clearly differentiated a breakable link, and it is not a J-hook. It does not deform.

THE COURT: Wait. And I actually find that evidence compelling, but I just, in terms of -- I mean, that is all extrinsic evidence. Correct? There's no extrinsic evidence to that effect.

MR. FLANNERY: I don't believe that the Federal Circuit has said it's extrinsic or intrinsic.

THE COURT: Well, you've already told me. Didn't you answer? I mean, I thought you were being pretty candid, it's extrinsic evidence.

MR. FLANNERY: Yes. I think because it is not in the prosecution of the U.S. patent, that technically, by those terms, it's extrinsic evidence, but when you view the Federal Circuit case law in Apple v. Motorola and some other cases, they do tend to consider it as part of a prosecution in the patent family.

Sorry for the confusion. I just meant to add

that caveat, that as well as extrinsic, it is important to be clear.

THE COURT: Okay. All right. So let me hear from the plaintiff on this, this question of whether, you know, what is the status of the statements made during the prosecution of the foreign counterpart.

Boston Scientific, you agree. It's appropriate for me to consider that. Right? I mean, the Federal Circuit has done that in a number of cases, including Apple against Motorola.

MR. FLANNERY: I think it would be inappropriate in these circumstances, respectfully, Your Honor, because I think the intrinsic record teaches us more, or teaches one of ordinary skill in the art about what a breakable link is.

And if I could refer to slide 17, the Examiner, when examining the claims over the Gourlay reference, found that this opening and closing of these arms 20 was inherently a breakable link. That's what the U.S. Examiner, that's what the U.S. Examiner said here, so that's something more than just a fracturing.

And Boston Scientific -- and this is even in plaintiffs' slides and in their brief -- Boston Scientific took the position, okay. Even if those moveable arms are inherently breakable, we've got another way to distinguish

the Gourlay reference. That's acquiescence. That language, Your Honor, even if, that's a statement of acquiescence. That's not a statement of accepting a disclaimer. The Patent Office said that those arms 20 are inherently breakable and Boston Scientific said, okay. Well, even if that's the case, we're going to distinguish the Gourlay reference based upon the link being broken by a first predetermined tensile force.

So there we have a statement from the -- this is what the public can rely on, a statement from the Examiner that that type of link is inherently breakable, and Boston Scientific, using language even if, acquiesced in that.

So right there we have intrinsic evidence that is teaching us or teaching one of ordinary skill in the art in the context here that a breakable link can be something more than fracturing. That's the U.S. evidence and the foreign prosecution cannot trump that, Your Honor. It's a single statement from the foreign prosecution.

I have the binder in front of me and the appendix is many pages long, double-sided. We don't need to consider that when U.S. intrinsic evidence tells the scope of what a breakable link is and it does not limit it to something that fractures.

THE COURT: Okay. I'm going to construe the term breakable link adapted to be broken as "a component of

the device designed to mechanically fail by fracturing at a predetermined tensile load."

Boston Scientific argues that breaking the link does not necessarily require fracturing the link. The link could instead break through deformation. As evidence that the breakable link can break by deforming, Boston Scientific cites embodiments in the written description that include a link called the J-hook that can release from the clip by deforming to a straightened position at a predetermined tensile load. And Boston Scientific asserts that the breakable link claimed in dependent claim 3 is the deformable J-hook.

I find, however, that the specification does not establish that the breakable link can break through deformation. The claims reveal that the patent differentiates between the deformable J-hook and the breakable link claimed in claim 1.

Claim 12 of the '245 patent differentiates between the breakable link and the J-hook when it recites "a frangible link wherein the frangible link is at least one of wire reversibly deformed into a J-hook and the breakable link, wherein the J-hook is able to be straightened by the first predetermined tensile force, and wherein the breakable link is able to be broken by the first predetermined tensile force."

Moreover, the specification never describes the J-hook as breaking, only as deforming or straightening. Boston Scientific also argues that the breakable link term should receive the same construction that this Court gave the term frangible link as used in the '371 patent in the Cook litigation.

So Boston Scientific does not persuasively explain why I should construe breakable link as having the same construction as a different term in a different patent. Also, the patent frequently calls the J-hook a frangible link, and as disclaimed above, the patent treats the J-hook and the breakable link as discernibly different components. I refer you specifically to column 7, lines 24 through 25 of the '245 patent.

Although the term frangible link may include the breakable link, a frangible link is not equivalent to the breakable link because the frangible link clearly includes the J-hook.

Now, I will limit the term breakable to breaking via fracture because Boston Scientific disclaimed the scope of the term during prosecution of the '245 patent's foreign counterpart, which is at EP199. And as far as whether it is appropriate to consider that, I do so based on the Federal Circuit's decision in Apple against Motorola, 737 F3d., 1286. And I think there's other case law incidentally in

which the Federal Circuit has considered and found it to be important, disclaimers and statements made during the course of the prosecution of a foreign counterpart to the U.S. patent that has been asserted in the litigation.

During the prosecution of the EP199, Boston Scientific distinguished the invention from prior art on the grounds that the prior art did not discuss or even suggest a breakable link adapted to be broken, but instead disclosed a deformable link in the form of a hook 51, but not a breakable one.

The European Patent Office accepted the argument, stating that claim 1 is characterized over the prior art by the presence of the breakable link, which breaks under a predetermined tensile force of a frangible (weakened, brittle) portion instead of a bendable in (or rather straightenable) engaging portion.

Moreover, in an opposition proceeding against the '199 European patent, Boston Scientific asserted that the claim thus requires the link to be broken wherein to break is clearly given the meaning and scope, which the term normally has in the art, i.e., that fracture of a link into two or more pieces takes place.

Finally, I will construe the term adapted to be broken as designed to be broken rather than capable of being broken. Claim language establishes that the breaking

results from a design choice because it explains that the breaking occurs at a predetermined tensile load. I refer the parties to the In re: Man Machine Interface case at 822 F3d., 1282, in which the Federal Circuit construed adapted to as "made or designed to. "

All right. The next term is sheath. And you all can't agree to just let the jury have this and just leave it as plain and ordinary meaning. Is that right, plaintiffs?

MR. RHOAD: I think we would be -- we would be fine with plain and ordinary meaning. We think that's -- we simply proposed the -- oh, I'm sorry.

Let me just state for the record, this is Bob Rhoad. Good morning, Your Honor. And, you know, we simply proposed the construction that the Court gave this term in the Cook case, and we think the Court gave the ordinary meaning construction, and we are certainly, I think, happy to just leave it as the plain and ordinary meaning of the term sheath.

THE COURT: How about the defendants?

MR. HIGGINS: Your Honor, for the '245 patent alone, we are fine with plain and ordinary meaning on sheath and will address it separately for the other patent.

THE COURT: Okay. Well, that was an agreement, so there's no need for me to explain a ruling. And so the

parties have agreed that for the '245 patent, I'm going to give sheath its plain and ordinary meaning.

All right. I think the next disputed term is coupled to the sheath in claim 1 of the '371 patent. Is that correct?

MR. RHOAD: Yes, Your Honor.

THE COURT: Okay. Let me hear from Boston Scientific first.

MR. RHOAD: Certainly, Your Honor. Again, this is Bob Rhoad.

So this is a term -- for the term sheath, we argued that, proposed that the Court adopt the same construction that it did in the Cook case, and here we are arguing for a different construction than what the Court had adopted in that case, and it's really -- we respectfully submit that the Court found the disavowal that was not clear and unequivocal and that the patentees, in fact, never did disavow the ordinary meaning of the term coupled to the sheath.

We look at the claim term in context, and if Your Honor has our slides available, on slide 24, we show the term in context. It's referring to a bushing being coupled to the sheath, and I don't think there's any dispute that our construction, proposed construction, reflects the ordinary meaning of the term coupled to being linked

together, connected, or joined to the sheath. And, in fact, defendants' construction includes that same language.

So the dispute really here is whether or not there's anything to limit that ordinary meaning, and their argument is based on a disavowal.

So the question is: Is the prosecution, was there any disavowal of claim scope that would result in a disavowal of not slidable within the sheath. And on slide 25, I think we have the key issues here. And so on the top of 25, we see the figure showing the Kimura device and the alleged disavowal occurred in connection with the patentee distinguishing that Kimura device.

And so if we look at that figure, we've highlighted the relevant components. What the Examiner said was, the "bushing" was the No. 12, the hooked section of No. 12 highlighted in blue there. And we see the sheath is sheath 8 that's highlighted and sort of reddish, pinkish, and in yellow we have the control wire.

So, again, the claim language is the bushing coupled to the sheath. And so the Examiner said that the -- what he was calling the bushing, the blue, hook Section 12, is coupled to the sheath 8, the red section. And we see in the figure what it is, what it is clearly connected to, joined to, is the control wire 7 in yellow. We have an arrow pointing that out for Your Honor.

And so that's the Kimura reference that the patentee was distinguishing. And if we look in the paragraph below that on slide 25, this is the paragraph that the Court in the Cook case had relied on as defined a disavowal.

And if we look at what they say here, they say, the Examiner analogizes hook Section 12 to the claimed bushing, and they make essentially four statements.

The first one is that it can be seen that the hook section is coupled to the control member, not the sheath. So, again, that's saying the blue hook section is connected to the yellow control wire, and that's clearly true, and they are saying not the sheath.

So the patentee is saying that when you look at the Kimura device, it is clearly not coupled to the sheath, not coupled in the ordinary meaning of it. It's not joined to, connected to in any way.

THE COURT: I'm sorry.

MR. RHOAD: And they say that --

THE COURT: Can you just stop for just one second? All right, sir?

MR. RHOAD: Certainly.

THE COURT: I'm trying to find a picture of 3 B as opposed to 3A.

MR. RHOAD: That is Exhibit D. Do you have the

exhibits handy?

THE COURT: I do. Exhibit D?

MR. RHOAD: And it might actually be in our brief as well. Yes. That's also -- it's highlighted in, on page 58 of our brief.

THE COURT: Okay. Hold on one second. Figure 3B. Yes. Okay. Okay. I've got it. Yes.

MR. RHOAD: Yes. Okay. So then the second statement they make after saying it's connected to the control member seven, not the sheath, they say, the hook section is --

THE COURT: Well, wait, wait, wait.

MR. RHOAD: Is not --

THE COURT: Can you stop?

MR. RHOAD: Yes.

THE COURT: Can you stop for a second?

MR. RHOAD: Yes. And then leading into 3B. Yes.

THE COURT: It says, as you pointed out, it says, as can be seen in Figure 3B, but when I look at 3B, you are saying there's no coupling to the sheath in that? I mean, that looks like a very different picture than 3A.

MR. RHOAD: So 3B is essentially -- 3A you have pulled proximally on the wire 7. So the yellow, you're pulling that to the right.

THE COURT: Right.

MR. RHOAD: So you have now pulled it part of the way in there.

THE COURT: Right.

MR. RHOAD: Okay. And then 3C shown there, you've then pulled it even further in. And the patentee's point is saying even looking at 3B, what it is coupled to is the wire. The wire, if you push and pull the wire it's coupled to, the hook section.

And so they go on to say it's not coupled to the sheath at all. In fact, it's slidable in the sheath just as control member is, in fact, slidable.

So you can -- the yellow control wire 7, you know, you can push that in, out, in, out. You can pull it all the way out if you want. You can push it all the way out. It's not coupled to the sheath. It's just fully, you can just -- you can move it. It's not coupled at all. Again, as shown in 3A.

3B is the same exact embodiment. It's just shown having pulled it partially within the sheath. And I think nobody would say that the control wire is coupled to the sheath, and in the same way, just because, and it's not because you can slide it within the sheath. It's because it's not coupled to, it's not joined.

In Figure 3B, it is, it has been pulled within

the sheath, but it's not coupled to the sheath. It's not joined to the sheath. It's not connected to the sheath. It's just --

THE COURT: All right.

MR. RHOAD: -- within the sheath.

THE COURT: Okay. Anything else?

MR. RHOAD: No. I think our argument is that, yes, if you look at this paragraph, there's nothing that disavows, disavows being slidable in the sheath, so that's our argument.

THE COURT: Okay. Let's hear from the defendant.

MR. PEARCE: Your Honor, this is Van Pearce on behalf of the defendants.

As plaintiffs' counsel pointed out, this was an issue that was thoroughly considered in the prior litigation. I'm sure that Your Honor has read the opinion and Judge Burke addressed all of these arguments that plaintiff made.

What it really boils down to is they distinguished this reference on several grounds, one of which was that the bushing that was found in the prior art was not slidable within the sheath. They are held to those words. The fact that they maybe could have chosen to distinguish the reference on narrower grounds if that was an

option doesn't matter. We hold patentees to what they actually said, not what they could have said. And as Judge Burke found, this was a clear and unambiguous statement.

I will point out that plaintiffs could have objected to that ruling in the earlier litigation and chose not to.

So we submit they certainly have not shown any sort of clear error or manifest injustice here that would give the Court a reason to reconsider that prior ruling.

THE COURT: I'm just trying to understand why that's relevant to me.

MR. PEARCE: Why the objection is relevant or lack of objection is relevant?

THE COURT: Yes.

MR. PEARCE: Yes.

THE COURT: Why is it relevant?

MR. PEARCE: Only in the sense that this is an issue that was thoroughly litigated and they didn't take advantage of all of their opportunities to try to address that previously.

The main point --

THE COURT: Are you saying this is res judicata or collateral estoppel? What do you mean?

MR. PEARCE: No. We were saying this would be a situation where given that there was a prior ruling on this

term from another Judge of this Court, we do think that they would need to show the standard for reconsideration, which they have not done here. But --

THE COURT: And so help me out. I'm trying to understand that. Can you flesh that out for me? So a Magistrate Judge in another case made a ruling and you are saying that I'm bound by that Magistrate Judge's determination unless they come in and show that he was clearly erroneous?

MR. PEARCE: Well, Your Honor, that ruling was adopted.

THE COURT: So another District Court, another District Court Judge, for argument's sake, held that. I'm still trying to understand the argument that their failure to seek reconsideration somehow -- and that I can only now rule against that position if I find that there was clear error. Again, if you could tell me the legal argument so I understand it.

MR. PEARCE: Sure, Your Honor. The legal argument is there was a prior ruling that was adopted by the District Court Judge. Plaintiff expressly, as I understand it, is asking you to reconsider that ruling. And we believe that the standard for reconsideration should apply given that they are asking for a reconsideration of a prior construction from -- in a different case, but a prior

construction of this Court.

That said --

THE COURT: I'm trying to understand. So that's collateral estoppel. Is that what you are saying?

MR. PEARCE: I'm not sure that it's collateral estoppel because there's not a final judgment in the case.

THE COURT: So what is it? Help me out. Is it not res judicata, it's not collateral estoppel. What is it that I'm somehow limited in any way by a ruling of another District Court Judge or Magistrate Judge? If you could give me the legal argument, that's all I'm looking for.

MR. PEARCE: Sure. It's the Third Circuit case law, for example, on seeking reconsideration, which I'm sure Your Honor is familiar with.

If you are seeking reconsideration of a prior ruling, then typically --

THE COURT: That's in my Court, so I get that. If I had made a ruling and they -- if I ruled today and next week they sought reconsideration or you sought reconsideration, I get that, but I don't have a motion for reconsideration. I'm just trying to understand legal argument to what you are saying.

MR. PEARCE: It's a bit of an unusual situation, I will grant that, given that it was a prior ruling, it was not by Your Honor, it was by another Judge in this court,

and the plaintiff is asking for --

THE COURT: Well, wait. When you say this Court, again, I'm going to push on this because you brought it as your very first argument, so what is the legal basis? You know, do I have a motion for consideration before me?

MR. PEARCE: I believe you do. I think this is a motion --

THE COURT: This is very -- okay. So do you know of any case where I've got a motion for reconsideration in a litigation and the motion is brought for me to reconsider a ruling in another case? What Federal Rule of Civil Procedure would cite that?

MR. PEARCE: I don't have the case. I will grant that this is an unusual situation given what transpired here with different lawsuits pending before four different judges involving the same patent.

I do want to turn the focus to --

THE COURT: Well, I'm not going to let you turn to anything. I want you to answer my question because you decided to lead with this argument, so help me out.

Just so I understand, you are not saying it's collaterally -- it's not a collateral estoppel argument. You're saying that. Right? You are saying it's not res judicata. You are saying it's effectively a motion to reconsider. And can you point to any case or any civil rule

of procedure, rule of civil procedure that would guide me in this regard and that would provide a legal basis for your argument?

MR. PEARCE: Your Honor, other than the general standard for reconsideration, I don't have a case that deals with this precise situation.

THE COURT: Okay. So you've got a general standard for reconsideration under what rule? What rule are we talking about?

MR. PEARCE: This would be under the case law of the Court. For example, the Third Circuit case law dealing with requests for reconsideration.

The other point that I would make, Your Honor --

THE COURT: Can you point me to any Third Circuit case or Federal Circuit case where the Court considered a motion for reconsideration in the particular civil action and where the Court was asked to reconsider a ruling of another Judge in another civil action?

MR. PEARCE: I do not have a case cite for that particular proposition, Your Honor. I will point out that in Boston's reading, to some degree, the reason why we phrased it this way is because Boston said in their brief that they were respectfully requesting that the Court revisit its earlier construction. That's on page 56 of the joint brief, for example.

So I did not, or I understood that they were making this point, that they were asking the Court to revisit an earlier construction of the Court, and based on that, we cited the case law dealing with reconsideration.

THE COURT: All right. Why don't you argue the merits of your position.

MR. PEARCE: Sure. The merits of the position are in the C section of the prosecution that's at issue here. The patentee made a number of statements to distinguish the prior art. One of those statements was that the bushing in the prior art is not slidable within the sheath. That was a clear statement that coupled to the sheath, the bushing coupled to the sheath would not encompass a bushing that is slidable within the sheath. And the fact that the plaintiffs made other statements to distinguish the prior art on other grounds does not get them out of disavowal. There are a number of Federal Circuit cases to that effect. Statements that are actually made are what the public is entitled to rely on as part of the public notice function of the prosecution history.

The most that plaintiffs are saying here is that they have said more than just that it's not possible within the sheath and therefore they shouldn't be held to that statement, and we submit that's inconsistent with the case law.

THE COURT: So I agree with you on the merits and I'm going to construe the term accordingly. During the prosecution, the Examiner had rejected the claim containing the phrase coupled to the sheath under the prior art reference Kimura. Boston Scientific responded that its invention differed from Kimura, because in Kimura, the bushing "is not coupled to the sheath at all and, in fact, is slidable inside the sheath." And by referring to the ability of Kimura's hook section to be slidable inside the sheath, it's evident that it is not coupled to the sheath at all. Boston Scientific clearly disclaimed a construction of coupled to the sheath that allows for sliding within the sheath. So I agree with the defendants on that.

Okay. What do we have next?

MR. RHOAD: Your Honor, this is Bob Rhoad.

We have sheath again in the other patent family, the '371 and '725.

THE COURT: Okay. Let me hear from the defense on that.

MR. HIGGINS: Your Honor, this is Chris Higgins again.

One thing to point out here is that the term, this term was proposed by plaintiffs and they just proposed the term sheath. Defendants' position is that the term should be construed in the context of its entire limitation,

so the entire claim element should be construed, because when you look at the entire claim limitation here, it makes clear that the sheath that they are referring to must be slidable, and the reason is, if you look on slide 37 of our presentation, the sheath must extend to the target portions of tissue. And the feedback on the '725 and '371 patents disclose only two sheaths the first is an inner sheath and the second is an outer sheath.

Now, both are slidable, but only the outer sheath as we've depicted on slide 38, only the outer sheath extends to the target portion of tissue, and there's a specific reason for this. When you're inserting the device through the scope, this outer sheath covers the clip to prevent it from opening even when it exits the endoscope and goes into the patient, so you don't tear any tissue. When that outer sheath reaches the target portion of tissue, it's retracted, so then the clip arms can open.

And if you look at in slide 38 what we have depicted here, the outer sheath is in green. What plaintiffs are saying is the sheath is called a wire coil by the patent. It's not termed a sheath. And it does not extend to the target portion of tissue, nor can it, because it stops before the clip assembly.

Based on that disclosure, it's our position that the claim language is clear, that the sheath here must be

slidable, because if the sheath were not slidable, this would result in an inoperable device. And the Federal Circuit has made clear in AIA Engineering, 657 F3d., 1264, that "a construction that renders the claimed invention inoperable should be viewed with extreme skepticism."

Based on the clear language in the claim and the result of what would be if you go with plaintiffs' construction of an inoperable device, that supports here that the plain meaning means a slidable sheath.

THE COURT: Okay. Can I hear a response?

MR. RHOAD: Certainly, Your Honor. This is Bob Rhoad.

Yes. So I think we agreed that the ordinary meaning of sheath is not what they are proposing. There's no requirement in the ordinary meaning of sheath that it be slidable. What they are seeking to do is limit it to a particular, to particularly what is described in the patent as inner sheath 132 and over sheath 150, and they have basically no answer for the fact that other sheaths are certainly possible. They have no claim of disavowal or disclaimer. There's no lexicography. They are not saying -- they are not saying that there was any definition of sheath provided in the specification or anywhere in the intrinsic evidence limiting it to them. And, in fact, they have no answer, for example, for dependent claim 3, which

says, wherein the flexible sheath is formed as a wire coil, and it's undisputed that the only coil in the patent that is described that could be a sheath is coil 130, which is described as a single coiled wire, whereas inner sheath 132, and this is shown on our slide 21, the things that they are saying are the only sheaths of the '725 patent, neither of them are described as being a single coil wire. Rather, they are described as being low friction materials like Teflon.

So they have no answer for claim 3, and so there is no basis, as Your Honor mentioned earlier, you know, there's only -- you know, you apply the ordinary meaning unless there's lexicography or disavowal.

They raised this inoperability argument for the first time on surreply and that's their primary argument, but there's no support for the notion that it's inoperable. They don't have any evidence that it's inoperable, and it's really a construction of a term that's not at issue, what it means to extend to a target portion. And they seem to suggest that that means the sheath has to go and touch the target portion, and that's not something that was identified for construction, and we would certainly disagree with that. The term that was identified for construction was the term sheath, and we think it should be given its ordinary meaning.

In the Cook case, the Court noted the similarities between these two patent families. That case involved the same two patent families that we have here, and it noted the substantial similarities between the clipping devices, respective filing dates, that they both came out of the same research program at Boston Scientific, et cetera. And so there's no reason to apply anything other than the ordinary meaning in these patents as well.

THE COURT: So I agree. I think it's well stated, the arguments. I'm not going to repeat them, and so I'm going to agree with Boston Scientific's proposal and construe the term as "one or more components of the delivery device that even close a control wire."

All right. We're at the next term to the, I believe the clip assembly, right, for the terms? Is that right?

MR. FLANNERY: Yes, Your Honor.

THE COURT: All right. Let me hear from, I will hear from plaintiffs on this.

MR. RHOAD: Thank you, Your Honor. This is again Bob Rhoad.

So the term we're dealing with here is clip assembly, and it's, the term assembly in particular is a broad generic term, you know, referring to essentially a group of components that perform some function. The

specification refers to a number of different assemblies. It refers, for example, to a handle assembly. It refers at one point to an over-sheath assembly, and relevant here is the term clip assembly.

And in the context of the patents, the term clip assembly, you know, essentially refers to the clip arms that form the clip and do the clipping, the grasping of the tissue, and the components that cause them to open and close, and then you move the control wire.

This is reflected -- we see that, for example, on our slide 28, if you have that handy, where we cite in the '725 patent in column 7 that it discusses that the clip assembly contains the mechanism that converts the proximal and distal movement of the control wire into actions necessary to deploy and release a hemostatic clip.

So essentially, again, what that is saying is it's more than just the clip arms. It's also the clip arms and the components that convert that movement of the control wire into opening and closing the clips.

So the clip assembly doesn't include the control wire, the control member recited in the claims, but it includes the clip arms and those things that convert the movement of the control member into opening and closing, and that's actually reflected also as shown in claim 28 in the claim language, which says that the clip assembly must be

configured to be operably moveable between a closed configuration and an expanded configuration, and it goes on, and that's done in response to movement of the control member.

So we contend that the Court should give this term its ordinary meaning, and so we suggest adopting, and in view of Your Honor's construction of the term clip in the '245, we would be willing to accept an assembly that has a multi-legged grasping device. And so it's really that. It's the clip and the components and the assembly that is with that that controls its opening and closing.

So that's the ordinary meaning of the term clip assembly. The patentee used the broad general term clip assembly, and their case law makes clear they are entitled to the full breadth of that broad, ordinary meaning absent disavowal or lexicography.

And if we leak at the defendants' construction --

THE COURT: Well, let me just -- I appreciate it. In the interests of time, I'm inclined to go with you, so let me hear from the defense.

MR. PEARCE: Your Honor, this is Vann Pearce for the defendants.

Plaintiffs' counsel I believe just said that the clip assembly is more than just the clip arm, and we

certainly would agree with that. The problem with the plaintiffs' construction is, and particularly as they also claimed in their briefing, it could be met by just a clip and nothing else. It would allow for other things.

And it --

THE COURT: Wait. It's an assembly having a clip, but I mean, that to me, it has to have something else.

MR. PEARCE: I absolutely agree.

THE COURT: So I'm not sure why you can't live with -- I mean, my take on this is we should construe the term as "an assembly having a clip, i.e., a multi-legged grasping device provided in the capsule." That would be for the first claim.

And then for the second claim it would be, "an assembly having a clip, i.e., a multi-legged grasping device received within the lumen of the capsule."

MR. PEARCE: So on that point, the way we understood the plaintiffs' construction first was that the clip could, the clip assembly could include more than a clip, but would not necessarily have to.

And I'm looking at, for example, in their brief, they said that the clip assembly may include other things than the clip.

So certainly --

THE COURT: Well, his construction is what I

just said. He agreed to it, an assembly having a clip. I mean, assembly, you've got to have something else. Right? I mean, otherwise you just say, it's clip. Right?

MR. PEARCE: Right. So we certainly would agree with that.

And then the next question would be: What is that assembly? And our position on that is that during the IPR proceeding, the patentee explained what the clip assembly includes. For example, at page 891 of the Joint Appendix --

THE COURT: Right. But let me just ask you. I didn't think that that was so clear that they disavowed the scope, but that it has to have all the specifics of the things. I mean, let me ask plaintiff. Look, it has an assembly. It means something then. It's not just a synonym for clip. Right, Boston Scientific?

MR. PEARCE: I think that is general generally right. This patent generally uses the term clip assembly and doesn't refer to just the clip, but, yes, we agree that it's the assembly having a clip. We certainly agree with Your Honor's proposed construction.

THE COURT: Right, but if you tried to argue in front of the jury, hey, this is a clip, and if you tried to suggest to the jury that -- I mean, if the defense responded it isn't just a clip, it's an assembly having a clip, where

is the assembly? And if they said in front of the jury, hey, plaintiff, point me to the assembly, your response could not be, oh, the assembly is the clip. Right? It's something more.

MR. PEARCE: Yes. It includes, like I said, the mechanism that converts the movement of the wire into opening and closing the clip legs. You know, I hesitate to --

THE COURT: So let me stop you there.

MR. PEARCE: Referred to the device as a clip, but, yes.

THE COURT: So let me just stop you there because I think we might have agreement. I may not even have to construe this.

Defense having just heard what counsel stated, are you good with if I construed it as, I construe clip assembly provided in the capsule as "an assembly having a clip, i.e., a multi-legged grasping device provided in the capsule"?

MR. PEARCE: So, Your Honor, I think plaintiffs' counsel was just saying that the assembly there is the mechanism that converts the movement of the control wire into the clip opening and closing. There are words to that effect in their brief.

We would feel better I think to get this point

across more clearly if that was part of the construction, at least, this mechanism to open and close the capsule language. Excuse me. Open and close the clip.

THE COURT: Well, I don't think he has to limit himself to that. What is the basis of limiting the definition? Where is the clear and unequivocal disclaimer to that?

MR. PEARCE: Well, that is -- it's my understanding that's not really a point. Maybe I'm misunderstanding plaintiffs' point, but I didn't know that that was really a point of dispute. I thought that is what they were saying the clip assembly was.

THE COURT: I could be really -- I'm often obtuse, and I'm sorry if I am, and it's especially hard on the phone.

I think the line of discussion began with a legitimate, I think, concern that you raised, which is that, hey, this has got to be more than a clip, and, you know, you didn't want this to be just left. Your concern was my proposed construction, an assembly having a clip was that, but they are going to say it's just a clip and how do you counter that?

And I think my point was that, well, I don't think they can say that, because the assembly is something different than clip. It's a clip assembly. And I thought,

I think what we got out from plaintiffs' counsel was that if we were in front of a jury and Boston Scientific argues, hey, here's the clip and the clip is the same thing as the clip assembly, you know, that wouldn't be fair, and I basically was supporting the defense in this saying, yes, a clip has to be something more. I mean, rather, a clip assembly has to be something more than a clip. It's an assembly having a clip.

I thought that addressed the concern which started this whole line of the discussion, but now I see the defense is throwing a new thing into the discussion.

MR. PEARCE: Your Honor, I think it certainly goes a good way towards addressing our concern. Our view is that the assembly that's being talked about here is the mechanism that opens and closes the clip. That's basically our position in a nutshell.

So we certainly appreciate and agree that the clip assembly has to be more than a clip. In our view, we should take it one step further and say, what is an assembly? It's a mechanism that opens and closes the clip. That's what a clip assembly is.

THE COURT: Right. And you want me to define it as an assembly that contains clip arms, a tension member, a bushing and a yoke. Right?

MR. PEARCE: Yes. That is our position based on

what happened in the IPR.

THE COURT: Yes, but I mean what but happened in the IPR were the defendants made those statements in the context of a specific embodiment. Right?

MR. HIGGINS: Yes, but they were pointing to that embodiment when they were trying to distinguish the prior art. So if they are pointing to that embodiment as their explanation for why a clip assembly is different from a clip, we think it's appropriate to limit them to that.

THE COURT: That doesn't seem to me to be clear, unequivocal disclaimer.

All right. I'm going to construe the terms clip assembly provided in the capsule, and clip assembly received within the lumen of the capsule as respectively "an assembly having a clip, i.e., a multi-legged grasping device enclosed by a structural shell" -- sorry. "A multi-legged grasping device provided in the capsule. Let me start over again.

And then I'm going to construe the second term as "an assembly having a clip, i.e., a multi-legged grasping device received within the lumen of the capsule."

All right. I don't think the specification, it does not define or disavow the full scope of the first part of the disputed term, clip assembly, and therefore I construe clip assembly according to its plain and ordinary

meaning as an assembly having a clip, i.e., a multi-legged grasping device.

The defendants seek to require that the assembly contain clip arms, a tension member, a bushing and a yoke. I don't believe that construction is supported by the intrinsic evidence.

Defendants assert that Boston Scientific told the Patent Office in an IPR that the clip assembly must include clip arms, a bushing, a yoke and a tension member that are encased in a capsule, but the statements they cite establish only that in the context of a particular embodiment as being discussed, those elements were part of the particular clip assembly. And I reference Joint Appendix at pages 1043 to 44, 1131 and 1197 to 98.

The defendants do not provide evidence that Boston Scientific disavowed the scope of the claim by limiting the claim scope assembly to that particular embodiment.

And the dependent claims establish that the yoke and bushing components that defendants argue must be part of the clip assembly are not included in the broad term clip assembly found in claim 1 of both patents. Claim 4 of the '371 patent recites a clip assembly that further comprises a yoke, and claim 2 of the '725 patent recites an apparatus of claim 1 further comprising a bushing.

All right. The next term is separable yoke. Let me hear from the defendants.

MR. PEARCE: Your Honor, this is Van Pearce again on behalf of the defendants.

There are two issues on this term, really. The first is that the yoke has to be a separable yoke. The second is, what is a yoke?

On the first point regarding separability, we would submit that the plain language of the claim is clear. It's a separable yoke. It's a piece or a component that is able to be separated.

If the yoke is permanently attached to another component -- and to back up for a second, the claims talk about the separable yoke as being connected to the connecting member and the control member. If the separable yoke is permanently attached to the connecting member, if it's inseparable from the connecting member, then it's not a separable yoke, it's not a separable component.

In the plaintiffs' reply brief, they said that the separable yoke does not have to be separated from the control member. We submit that that is contrary to the plain language of the claims. It's also contrary to what the specification teaches.

If you go to the specification, there's no sort of redefinition of separable as something that can be

permanently attached to another piece. Instead it says that if the yoke cannot separate from the control member, the clip could be latched onto the plaintiffs' tissue, but unable to be removed from the device, and that's something obviously to be avoided.

So that's the issue with separable. When it comes to the term yoke, there's no evidence that that term yoke has some sort of well understood ordinary meaning in the art. It certainly is not a term that is understood either in the art generally or used in the patent anywhere near as broadly as what the plaintiff is proposing.

The plaintiffs' proposal is that a yoke can be any component that holds the pieces in place. There's just simply no evidence of that. To the contrary, during prosecution of one of the earlier patents in the family, the applicant repeatedly looked at other pieces of prior art that the Examiner said had a yoke and said, no, no, that's not a yoke. For example, the Sudiyama reference, the plaintiff said that no element of it was analogous to the yoke in any way. Instead, it used a hook or similarly shaped component.

So clearly they have made it plain that a yoke is not any component no matter how it's shaped. At a minimum, it cannot be a hook or a similarly shaped component based on the disavowal of the Sudiyama reference or the

statements about Sudiyama.

So when you have a situation where there's a term that is really a coined term, it doesn't have an understood meaning in the art, it is appropriate to look to the specification to define what that term means. The specification describes and shows a yoke as a component that has a socket on both ends.

So that's the basis for the yoke part of our construction, that this is a double-ended socket component, and those are really the two issues that we think are important to this term.

THE COURT: Okay. Thank you. Let me hear from your friend across the aisle.

MR. RHOAD: Certainly, Your Honor. Again, this is Bob Rhoad again.

Yes, Your Honor. I think it's important to look at the claim term in context, and I think it actually answers, I agree, that they have correctly identified the two -- the two central issues in dispute between us, and I think they are both answered specifically and clearly in the claim language itself.

So if you can turn, if you would, Your Honor, to our slide 37, highlighted in yellow, we have the general context for this claim term separable yoke. And so on the top part highlighted in yellow, it says, a control member is

releasably coupled to the clip assembly via a separable yoke. And so what this is telling us is that, you know, consistent with the ordinary meaning I think of yoke in terms of holding two things in place with respect to one another, it tells us that is exactly what they are referring to. They are referring to a yoke that is releasably, but holding two things in position with respect to each other, the control member and the clip assembly. You have two things that are together coupled to one another via the separable yoke.

And so it's invoking that ordinary meaning that we had proposed of, you know, component that holds two parts in position with respect to one another, but then it goes on and it says, the further part in yellow says, wherein the separable yoke includes. And so it's telling us, okay. What is that separable yoke?

So the first part we've highlighted in green deals with a shape or structure. They say it can't be a hook shape. It has to be this particular shape. They say it has to be a double-ended socket component.

That's not what the claim says. It says it has to have first and second yoke arms extending distally from the control member on opposite sides of the clip assembly, and that the clip assembly includes a connected member that extends between those two yoke arms coupling the yoke to the

clip assembly.

So the claim itself tells us what shape the yoke has to have. It has to have these arms in this particular configuration.

So, you know, their suggestion that, no, let's disregard that, let's say it has to be a double ended socket component. There's no basis for that, there's no disavowal, there's no lexicography, and the issue of the shape is answered by the claim itself.

The claim also deals with the issue of separability. It says, the first and second yoke arm being configured to be separated from the connecting member when subjected to a predetermined force by the control member when coupled the control member from the clip assembly. So it's telling us exactly how it's is separable and what it is separating from.

This notion that it can't be inseparable from another component, it has to be its own separate independent component that is not separated from anything else is actually contradicted by their own figure, which is their own Figure 24 shown in the brief, where we see that the ball, the ball component that is at the end of the control wire and a portion of the control wire actually remain with the yoke, so they remain throughout the operation, always coupled to the yoke.

So the yoke is never separated in the embodiment they themselves rely on from the ball 140. So, in fact, there is -- it doesn't have to be separated from every other component as part of the operation. It remains connected to ball 140.

So it's answered by the claims, and their assertion is, in fact, contradicted by their own embodiment. And, again, as far as their claim that it would somehow be inoperable, they have no basis for that. There's nothing in the record. They raise it improperly for the first time in the surreply, and there's nobody saying if you simply pulled back, again, looking at Figure 24, if you simply pulled, that the yoke just went with the control wire and was pulled out of the patient's body, there's no reason why that would be inoperable. The yoke at that point is not involved in any way in keeping the clip closed, in place, and so there's simply no support that it's inoperable.

So for that reason, we think there's no disavowal or lexicography that would limit the ordinary meaning and that the meaning that you get from the claim itself.

THE COURT: Okay. On this one I'm going to construe a separable yoke as "a separable component that holds two parts in position." That definition in my view is supported by the intrinsic evidence.

The claim language describes the yoke as connecting two parts, the control member and the clip assembly. The written description embodies the yoke as a component that holds two parts together. I'm looking at Figure 9 of the '725 patent, for example. And as defendants admit, it is undisputed that the yoke includes two ends that connect to two different components of the device. I point you to the joint brief at page 8.

Defendants asked me to construe the term separable yoke as a double-ended socket component of the clip assembly that during use is separable from the control member and from the connecting member.

Defendants have asked me to construe the term as a component to sockets on both ends, but they do not cite intrinsic evidence that clearly and unambiguously limits the yoke to a double-ended socket component.

The defendants cite embodiments in the written description of the yoke with sockets, but particular embodiments appearing in the written description will not be used to limit claim language that has broader effect. And I just read from Innova/Pure Water, Inc. against Safari Water Filtration Systems, Inc., at 381 F3d., 1111, a Federal Circuit decision from 2004.

The defendants also cite excerpts from the prosecution history of other patents in the same family, but

in those histories, the inventor did not unambiguously limit the yoke to a double-ended socket component. Indeed, the inventors never even used the word socket.

Defendants also asked me to rule that the yoke is part of a clip assembly, that the plain language differentiates the separable yoke from the clip assembly and thus establishes that the yoke is a separate component from the clip assembly.

Claim 1 recites "the separable yoke extending distally from the control member on opposite sides of the clip assembly, and the clip assembly includes a connecting member extending between the first and second yoke arms coupling the yoke to the clip assembly."

If the yoke were part of the clip assembly, the inventors would not have described the yoke as connecting to the clip assembly.

Finally, defendants asked me to limit the term separable yoke to be separable from the control member and from the connecting member, but although the claim language describes a separable yoke as "configured to be separated from the connecting member," it does not describe the yoke as separable from the control member, and also it's unnecessary to construe the yoke as separable from the connecting member because the claim already includes that language.

All right. I think, where are we next? Disconnecting member, I guess? The last term? Is that right?

MR. FLANNERY: This is Kevin Flannery, Your Honor. We have connecting member and then --

THE COURT: I'm sorry. Configuration.

MR. FLANNERY: Yes.

THE COURT: Sorry. All right. Let's deal with connecting member. Let me hear from the defendants.

MR. HIGGINS: Your Honor, this is Chris Higgins.

The connecting member, it's a nonce term that has no understood meaning in the art. It only appears in the claim language. It never appears in the specification. And the only thing we have that performs this function that is recited in the claim of connecting these parts together in the clip assembly is the tension member. And the tension member appears in the title of the patent. It appears repeatedly throughout the specification. In fact, every single embodiment of the feedback patents includes the tension member. It is a necessary component.

There is no disclosure of any embodiment functioning without the tension member. And if you look at page 55 of our slide deck, we have gone through each embodiment, every figure that we could fit on this page, and identify that every single figure has a tension member.

This device cannot work without the tension member present.

And to address arguments that plaintiffs have made, all they have said at this point is that the plain and ordinary meaning should apply, but they have never actually said what that plain and ordinary meaning is. All they said is, a person of skill in the art would understand what a connecting member is based on the claim language. There was no reason to further define it. But the claim doesn't tell us what the connecting member is. It tells us what it connects to, the yoke, but it doesn't actually tell us what it is and what it does. And in that situation where the claim language is unclear, it is appropriate to go to the specification and see what the supporting disclosure is. And once you do that, a term can't be construed broader than what the specification supports for that term. In this case, the only disclosure in these patents is the tension member.

Now --

THE COURT: All right. You broke off there. Can you say it again, that last sentence?

MR. HIGGINS: Sure. The only disclosure in the specification of any component that could be the connecting member is the tension member, and the Federal Circuit has found it's appropriate to read claims, and, in fact, you have to read them in the context of the specification,

especially when here connecting member has no ordinary meaning.

And the last thing I was a pointing out is that our construction recites tension member. We also have this additional language. We've included that because tension member was a disputed term prior in the Cook case. We added this additional language in line with what that construction was so there would be no confusion, but what we're pointing to here is the tension member.

THE COURT: Okay. I will hear from Boston Scientific.

MR. FLANNERY: Yes. Thank you. Back to Kevin Flannery now for these two terms.

So there's no clear and unequivocal limiting or disavowal of the claim scope of a connecting member to a tension member. Defendants don't even try to support that, really, and there's no lexicography here.

The argument that the tension member as disclosed in the specification is a necessary component and that the invention somehow wouldn't work without it is just that, it's attorney argument, Your Honor. They have no support for that. There's nothing in the specification. They have no, no statements from any experts or anything, so they are asking Your Honor to simply accept attorney argument for a point that they otherwise have no support

for.

They're effectively just trying to read the claim terms of a broad term connecting member onto a preferred embodiment, and there's simply no support to do that. There's no lexicography here. The fact that the tension member is in the preferred embodiments is not limiting.

As we know --

THE COURT: So what would you say to the jury? You know, you want to say plain and ordinary meaning. What's a connect member? What would you say? What is the plain and ordinary meaning?

MR. FLANNERY: It's a member for connecting things. Just like, Your Honor, we have dozens of terms in the patent and the claims that are at issue here that aren't being construed, and we don't -- obviously, we don't have to ascribe a meaning to all of those. This would be the same situation.

I think we wouldn't even need to be talking about this to the jury as long as Your Honor rejects the claim construction, I mean defendants' construction, because there's clearly connecting structure in their device. They just want it to be limited to this tension member that's in the specification.

So just as we have many other terms in the

claims that we're not ascribing any meaning to for the jury, we don't see that we have to ascribe one here. But if we're looking for a construction, it's a member for connecting things, as I think member is a classic patent law term, a term of art that nobody ever has problems with. It's a thing. It's some kind of structure.

So if Your Honor feels -- you know, we're trying to simplify things and eliminate defendants' construction, but we didn't feel the need that we have to go on and ascribe particular terms, words to it when Courts often just say at the end of the day, it's the plain and ordinary meaning.

But if you're looking -- if we need language, a member for connecting structure or something like that would be totally fine, Your Honor. It's defendants' construction that is the problem because it's not supported.

THE COURT: All right. Well, I disagree. I'm going to construe connecting member as a "tension member that connects the clip arms to the yoke and biases, a clip arm to an open configuration," because the specification clearly limits the term to that construction.

The title of the '725 patent is "Through the scope tension member release clip." The abstract of the '725 patent discusses "a tension member connected to the clip arms and biasing the clip arms towards an open tissue

receiving configuration and a yoke slidably received within the capsule and releasably coupled to the tension member."

The summary of the invention states that, "In one aspect, the present invention is directed to a hemostatic clip assembly with a tension member connected to the clip arms and biasing the clip arms toward an open tissue receiving configuration and a yoke coupled to the tension member."

Moreover, as defendants assert and Boston Scientific does not contest, all of the embodiments described in the patent contain a tension member.

When a patent describes the features of the present invention as a whole, this description limits the scope of the invention. I'm quoting here from Verizon Services Corporation, 505 F3d. at 1308.

Here, the patent's description of a present invention is having a tension member that connects the clip arms to the yoke and biases the clip arm towards an open configuration, and the consistent presence of the tension member in all of the patent's embodiments clearly limits the scope of the claims.

Similarly, in Ultimate Pointer LLC against Nintendo Company, 816 F3d., 816, it's a Federal Circuit decision from 2016, the Federal Circuit construed the term handheld device as being limited to a direct pointing device

because, "the specification repeatedly emphasized that the invention was directed toward a direct pointing system." The title of the invention explicitly stated that the invention is an eagerly deployable, interactive direct pointing system, and the written description repeatedly criticized indirect pointing.

The Federal Circuit held that Ultimate Pointer's argument that a Court may only deviate from the ordinary meaning when there is an explicit definition or disclaimer did not apply because the ordinary meaning of handheld device, when read in the specific context of the specification of the asserted patent, was limited to a direct pointing device. And that's what we have here.

So, all right. Last term. Closed configuration in claim 1 of the '371 patent and claims 1 and 12 of the '725 patent. Let's hear from the defendant.

MR. PEARCE: Your Honor, this is Vann Pearce for the defendants.

To start with, just looking at the claim language here, the claim language describes that the closed configuration is a configuration of the clip assembly, a clip assembly provided in the capsule and configured to be operably moveable between a closed configuration with the first and second arms and the clip assembly are drawn toward one another.

So to begin with, our first point here is that the closed configuration is the configuration of the clip assembly and not just the clip. As we discussed earlier, the clip assembly is something that's more than the clip.

So our position on this is that the closed configuration of the clip assembly is the arrangement or cooperation of the components of the clip assembly that result in the clip arms being closed, but is more than just the clip arms necessarily being closed.

And what the patent discusses when it talks about configurations in the example is, this is from the '725, column 14, 15 through 15, 6. The configuration is a deficient configuration of the clip assembly where you have the capsule that is cooperating with the clip arms to constrain this clip arm. That's what we're trying to encompass with our construction here.

THE COURT: All right. And then Boston Scientific?

MR. FLANNERY: This is a situation again, Your Honor, where there's no clear and unmistakable limitation of this broad language to that particular embodiment in the specification.

THE COURT: I agree. I agree with you there. So then we boil down to the plain and ordinary meaning. I

mean, look. I don't think there has been any explicit or clear disclaimer in claim scope. You know, I'm inclined to construe it, and I would like to construe it as the configuration of the clip when its clip arms are closed.

What does Boston Scientific think of that?

MR. FLANNERY: We would accept that, Your Honor.

THE COURT: All right. And what about the defense?

MR. HIGGINS: Your Honor, if it was the configuration of the clip assembly when the clip arms were closed, that would be more consistent with the claim language.

THE COURT: All right. Well, hold on. Let me see if we've got an agreement here.

Can the plaintiffs live with the configuration of the clip assembly when its clip arms are closed?

MR. FLANNERY: Just making sure, Your Honor.

THE COURT: Yes, please. Yes, sure. Well, let's hear from plaintiffs.

Defendant, what is your alternative here? It would be the configuration of the clip assembly when its clip arms are closed. Is that right?

MR. HIGGINS: Well, I'm sorry. Could you repeat that? I didn't catch all of that.

THE COURT: So I take it on the table is the

possible agreed construction of closed configuration to mean "the configuration of the clip assembly when its clip arms are closed."

The defense is good with that?

MR. HIGGINS: May we have one moment, Your Honor?

THE COURT: Please. Go ahead. Both sides take it. What is on the table is, "The configuration of the clip assembly when its clip arms are closed."

MR. FLANNERY: Plaintiffs agree, Your Honor.

THE COURT: I'm sorry. What? Plaintiffs agree to that. All right. What about the defense?

MR. HIGGINS: We'll accept it, Your Honor.

THE COURT: Okay. Great. We've got a stipulated claim construction. That's great.

All right. So I think that covers everything. My oral rulings constitute the rulings with respect to the construction of the limitations that were disputed.

I would like the plaintiffs to draft a proposed order, obviously run it by the defense that reflects my rulings today so we can have it in the claim chart going forward. And if you could get that to the Court within a week, would that be do-able, plaintiffs?

MR. FLANNERY: Yes, Your Honor.

THE COURT: And are there any questions or any

other issues that I need to address?

MR. FLANNERY: Nothing from plaintiffs, Your Honor.

THE COURT: How about from the defense?

MR. HIGGINS: Nothing from defendants.

THE COURT: Okay. Well, thank you, all. I enjoyed the briefs and the arguments, and stay safe. Thank you.

(Counsel respond, "Thank you, Your Honor.")

(Telephone conference concluded at 10:51 a.m.)

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